UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MICHAEL NGUYEN and KELLY NGUYEN, Individually And On Behalf of All Others Similarly Situated, Plaintiff, vs. NEWLINK GENETICS CORPORATION, CHARLES J. LINK, JR., and NICHOLAS N. VAHANIAN, Defendants.	**File No. 1:16-CV-3545-WHP** **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

1. Lead Plaintiffs Michael and Kelly Nguyen ("Plaintiffs") bring this federal securities class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of the purchasers of NewLink Genetics Corporation ("NewLink" or the "Company") common stock between September 17, 2013 and May 9, 2016 (the "Class Period"), against NewLink, its Co-Founder, Chief Executive Officer and Chairman Charles Link, Jr. ("Link") and its Co-Founder, President and Chief Medical Officer Nicholas N. Vahanian ("Vahanian")[1] (collectively, "Defendants") for violations of the Securities Exchange Act of 1934 (the "Exchange Act").

[1] Collectively, Link and Vahanian are referred to herein as the "Individual Defendants."

2. Plaintiffs allege the following based upon the investigation of Plaintiffs' counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by NewLink, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company and its executives, media reports about NewLink, and interviews with witnesses with knowledge of the allegations herein. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

OVERVIEW

3. This federal securities fraud action concerns a pharmaceutical company, NewLink, which misled investors regarding the commercial prospects, efficacy and clinical trial protocols of its single most advanced cancer treatment candidate algenpantucel-L (also known as HyperAcute Pancreas). During the Class Period, NewLink and the Individual Defendants told investors that the Company was developing a promising, revolutionary new cancer treatment with numerous advantages over existing therapies "to extend both survival and improved quality of life for patients with cancer."

4. Algenpantucel-L provided Defendants with the perfect opportunity to attract outside investment and infuse much-needed capital into the Company. Pancreatic cancer is a prevalent and deadly form of cancer that accounts for about 7% of all cancer deaths in the United States. Yet, because it qualifies as a rare medical condition, the Food and Drug Administration would grant algenpantucel-L with an Orphan Drug designation, which would offer the opportunity for exclusive marketing rights, clinical tax research incentives, and exemption from filing fees, which would further entice investors.

5. But in order to receive approval from the FDA, drugs and other medical treatments must first demonstrate safety and efficacy through a series of clinical trials. NewLink therefore initiated a series of clinical tests, including a critical Phase 3 trial called IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study), the goal of which was to test the overall survival of patients utilizing the algenpantucel-L therapy versus standard pancreatic cancer therapy. Defendants repeatedly assured investors that NewLink "initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival."

6. Contrary to these repeated public assurances, the Phase 2 trial results did not suggest that algenpantucel-L improved overall and disease-free survival. Given both its limited size and the fact that there was no control group, it would have been impossible for the Phase 2 trial to demonstrate such results. Nevertheless, Defendants initiated the Phase 3 IMPRESS trial, which allowed them to facilitate an initial public offering (IPO) and artificially inflate the value of NewLink stock through false and misleading statements, thereby allowing the Individual Defendants to make millions of dollars through suspiciously timed stock sales.

7. Throughout the Class Period, Defendants made numerous materially false and/or misleading statements and omissions regarding the promise of algenpantucel-L, the stringency of the IMPRESS clinical trial design; Defendants' assumptions made with regard overall survival endpoint for the trial; its likelihood of achieving positive results in its clinical trials; and regulatory clinical practice violations committed by those working on IMPRESS.

8. For example, Defendants stated: "We are confident in the stringency of this study design and the statistical power provided by the large number of patients participating in this trial as we enthusiastically look forward to the clinical results"; "We are encouraged by the apparent

lengthening of survival in the combined arms of this study…"; and dismissed concerns regarding non-compliance of their clinicians with Good Clinical Practice (GCP) requirements saying it was "a minor procedural issue involving one clinician."

9. These and similar statements and omissions caused the price of NewLink's common stock to rise from $17.07 on September 17, 2013—the start of the Class Period—to as much as $58.73 per share on April 9, 2015, an increase of more than 344%.

10. Unbeknownst to investors, however, these statements and omissions were materially false and misleading. For example, with regard to the stringency of the study design, IMPRESS included patients who were not even qualified to be in the trial. These inclusions allowed the Individual Defendants to obtain substantial cash bonuses tied to meeting IMPRESS enrollment targets. A well-placed former employee of NewLink who had personal discussions with Defendant Vahanian regarding the IMPRESS trial stated that NewLink had difficulty enrolling patients in the trial, and Defendant Vahanian pushed to include patients that did not meet the eligibility criteria of the trial.

11. That same employee also described pervasive regulatory documentation errors for the IMPRESS trial, explaining that NewLink did not hire anyone with regulatory experience, did not have quality control documentation procedures in place, and flouted regulations requiring that confidential patient information be kept in a secure room. So, while Defendants stated in March 2016 that GCP non-compliance was a one-off event involving a single clinician, one of the Company's own employees described pervasive non-compliance dating back as late as December 2014.

12. Moreover, Defendants repeatedly made false and misleading assurances to investors that the delays in IMPRESS patient deaths were due to the effectiveness of

algenpantucel-L rather than a miscalculation of the overall survival duration of patients using standard therapy (the control group). A longer survival rate for the control group would require an even longer survival rate for the algenpantucel-L group to meet the statistical significance thresholds needed to proceed to marketing and commercialization. So, when interim analysis milestones (occurring when a certain number of IMPRESS patients died) took longer than projections indicated, Defendants assured investors that their overall survival estimates of the control group were accurate and attributed the delay to an even greater than expected health benefit of algenpantucel. In reality, Defendants grossly underestimated the overall survival of the control group, which was the only reason for the delays in patient deaths; the algenpantucel-L group was actually doing worse than those undergoing standard therapy.

13. Rather than admitting the truth to investors regarding algenpantucel-L and its fundamentally flawed IMPRESS clinical trial, NewLink CEO Charles Link and CMO Nicholas Vahanian sold tens of millions of dollars in NewLink stock, while the stock was at its highest artificially inflated values. The suspicious timing and size of these stock sales lead to the strong inference that Link and Vahanian knew that the algenpantucel-L would not meet its necessary clinical endpoints. Link received over ***$24 million*** over the course of the Class Period for selling a whopping 753,001 shares, or ***81%*** of his holdings as of the start of the Class Period. Similarly, Nicholas Vahanian received over ***$12 million*** during the Class Period for the 325,173 shares he sold—including his largest sale of 60,000 shares for nearly $3 million that suspiciously coincided with the height of the stock's artificial inflation—which represented ***252%*** of his holdings as of the beginning of the Class Period. Moreover, these profits were achieved without spending a single dollar on NewLink stock at market prices during the Class Period. And perhaps the most suspicious aspect to their trading practices is that while they dumped huge

amounts of stock in dozens of transactions during the Class Period while the stock was at its highest values, neither Link nor Vahanian has sold a single share since.

14. The full truth regarding algenpantucel-L and the IMPRESS clinical study was revealed to the market on May 9, 2016, when the Company announced that algenpantucel-L did not meet the main goal in the Phase 3 IMPRESS study. Not only did the results reveal that the overall survival rate of the control group was approximately 50% longer than what was conveyed by Defendants, the announcement also revealed that patients with algenpantucel-L lived for a median of 27.3 months in the IMPRESS trial compared a median survival of 30.4 months for patients treated with standard therapies, indicating that algenpantucel-L may have nullified the benefits of standard therapies or actually ***harmed*** pancreatic cancer patients.

15. Upon the announcement, which occurred on May 9, 2016 after the market closed, NewLink shares plummeted from $16.50 per share at close on May 9, 2016 to close at $11.45 per share on May 10, 2016, a decline of over 30%. As investors digested the bad news, the price of NewLink stock continued to slide on heavy trading volume and closed at $9.71 two days later on May 12, 2016.

16. Shortly after NewLink's announcement, Adam Feuerstein, a senior *TheStreet* columnist who covers the biotech industry, stated that "NewLink deserves to be investigated for this disastrous pancreatic trial result. A 3-month OS [overall survival] difference in wrong direction is outrageous."

17. As a consequence of Defendants' materially misleading statements and omissions that obscured true facts revealed on May 9, 2016 resulting in a precipitous decline in NewLink's stock value, Lead Plaintiffs and the Class suffered significant losses and damages.

JURISDICTION AND VENUE

18. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. § 240.10b-5].

19. This Court has jurisdiction over the subject matter of this action pursuant to §28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

20. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b), as the Company's common stock trades on the NASDAQ, located within this District.

21. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

Plaintiffs

22. Lead Plaintiffs MICHAEL and KELLY NGUYEN, as set forth in their previously-filed certifications [Dkt. # 19-1], incorporated herein by reference, purchased NewLink common stock at an artificially inflated price during the Class Period, and were harmed when the true facts were revealed and the artificial inflation was removed from the price of the stock at the end of the Class Period.

Company Defendant

23. Defendant NEWLINK is incorporated under the laws of Delaware, maintaining its principal place of business at 2503 South Loop Drive, Ames, Iowa 50010. As explained

above, NewLink is a biopharmaceutical company that focuses on the development of immunotherapeutic products for patients with cancer. Throughout the Class Period the Company's stock traded on the NASDAQ under the ticker symbol "NLNK."

Individual Defendants

24. Defendant CHARLES J. LINK, JR. is a co-founder of NewLink and has served at all relevant times as the Company's Chairman and CEO. Defendant Link made materially false and misleading statements and omissions during the Class Period and personally certified all of the Company's financial reports issued during the Class Period. During the Class Period, Link sold 753,001 shares of his personally-held NewLink stock for gross proceeds of $24,403,151.

25. Defendant NICHOLAS N. VAHANIAN is a co-founder of NewLink, and has served at all relevant times as the Company's President and CMO. Defendant Vahanian made materially false and misleading public statements and omissions during the Class Period, and during that time sold 325,173 shares of his personally-held New Link stock for gross proceeds of $12,006,979.

FACTUAL BACKGROUND AND SUBSTANTIVE ALLEGATIONS

A. NewLink Business Overview and Initial Public Offering

26. Founded in 1999, NewLink is a clinical stage biopharmaceutical company focused on using cellular immunotherapeutic products for the treatment of cancer. NewLink has never manufactured any of its product candidates at a commercial level and therefore has never earned revenue from commercial sales of any of its product candidates.

27. While NewLink's portfolio included other treatments in nascent development stages such as small molecule IDO pathway inhibitors, the product candidate that NewLink used to put itself on the map was algenpantucel-L, a therapeutic vaccine for the treatment of

pancreatic cancer. Leading up to and during the Class Period, algenpantucel-L, or HyperAcute Pancreas, was NewLink's most developmentally advanced treatment candidate of the Company's proprietary HyperAcute Cellular Immunotherapy technology, which was designed to stimulate the human immune system to recognize and attack cancer cells.

28. The market opportunity for a pancreatic cancer immunotherapy provided NewLink with the perfect launching pad for attracting outside investment. Pancreatic cancer is a particularly prevalent and particularly deadly form of cancer. According to the American Cancer Society, about 53,070 people will be diagnosed with pancreatic cancer in 2016 and 41,780 people will die from the disease. Primary carcinoma of the pancreas accounts for about 3% of all cancers in the United States and is the fourth leading cause of cancer death in the United States, accounting for about 7% of all cancer deaths. Despite breakthroughs in biotechnology, most patients diagnosed with pancreatic cancer die from the rapid progression of their disease with a devastating 96% mortality rate.

29. Cancer immunotherapy, also called biologic therapy, research has exploded in popularity in recent years as an alternative to chemotherapy. Immunotherapy utilizes a more refined and individualized mechanism that can guide the body's immune cells, or T-cells, to specifically target and destroy cancer cells.

30. With respect to pancreatic cancer, scientists have shown that tumor cells produce a number of defective proteins or express normal proteins in highly uncharacteristic ways. The immune system fails to identify or respond to these abnormalities and the cancer cells are not attacked or destroyed for reasons not yet fully understood. NewLink proposed algenpantucel-L as a new way to stimulate the immune system to recognize the abnormal components in

pancreatic cancer cells and to stimulate an immune response that destroys or blocks the growth of the cancer.

31. In February 2010, NewLink completed enrollment of its 70-patient Phase 2 clinical trial for algenpantucel-L in surgically-resected (surgically removed) pancreatic cancer patients. The Phase 2 (and ultimately Phase 3) trials focused on earlier stage, resected pancreatic cancer patients because they tend to have better prognoses than patients with later stage disease due to their better nutritional and immune status and lower amounts of residual disease. The Phase 2 trial was an open label, non-randomized trial in which patients were given algenpantucel-L in doses of either 100 million or 300 million cells approximately twice a month for six months in combination with a standard chemotherapy-based treatment.

32. Importantly, the Phase 2 trial did not contain a control group. In other words, every patient in the Phase 2 trial received algenpantucel-L, and the only distinguishing characteristic between the two groups involved in the trial was the dosage amount. Moreover, the size and scope of this trial could only produce inconclusive results for efficacy. Only 26 patients were in the high dose group and 44 patients received the low dose, so even though the trial resulted in a one-year survival rate of 96% for the high dose and 79% for the low dose, these results were not statistically powered to lead to the conclusion that algenpantucel-L suggested improvement in disease-free and overall survival of resected pancreatic cancer patients.

33. According to NewLink, "based on encouraging interim data" from the Phase 2 trial, in May 2010 the Company initiated its Phase 3 clinical trial of algenpantucel-L. Soon thereafter, using the "encouraging" Phase 2 data and Phase 3 clinical trial initiation as a launching pad, NewLink submitted a registration statement to the SEC to undertake an IPO. And after several requests from the SEC for additional information regarding its business plan

and numerous amendments to its registration statement, NewLink issued its prospectus in November 2011, selling 6.2 million shares of NewLink stock at $7 per share, raising $43.4 million dollars for a company that had never—and to this day still has never—made a single dollar from one of its own drugs.

B. Phase 3 IMPRESS Study

34. The IMPRESS phase 3 trial was an open-label, randomized, controlled, trial evaluating 722 patients with Stage I and Stage II surgically-resected pancreatic cancer who had no detectable disease by a CT scan. Half the patients in the study, the control group, received standard chemotherapy based treatment. The other half of the patients received standard adjuvant therapy with 300 million cells of algenpantucel-L. The primary endpoint of the trial was overall survival with secondary goals of disease-free survival, safety, toxicity and immunological responses. Thus, in order for the trial to be a success, the patients receiving algenpantucel-L would need to live longer than the control group, which Defendants stated was "18, 19 months to low 20s at best" by a statistically significant amount.

35. NewLink conducted the IMPRESS trial under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration ("FDA"). An SPA is an advanced declaration from the FDA that an uncompleted Phase 3 trial's design, clinical endpoints, and statistical analyses are acceptable for FDA approval. Because pancreatic cancer is life-threatening condition and algenpantucel-L, if viable, would fit an unmet medical need, the FDA granted IMPRESS a Fast Track designation for expedited review, and because pancreatic cancer is a rare medical condition, the FDA also granted IMPRESS an Orphan Drug designation, which can carry financial incentives such as exclusive marketing rights, clinical tax research incentives, and exemption from filing fees.

36. The IMPRESS study had up to four major milestones. The first milestone occurred when all 722 patients enrolled in the study. The second, third and fourth milestones were periodic reviews of the data by an independent Data Safety Monitoring Committee ("DSMC"). As determined by the SPA, the first interim analysis would be conducted when 222 patient deaths were reported for the study. If the data revealed that the overall survival of algenpantucel-L patients exceeded that of the control arm with a statistical significance with approximately a 99.5% likelihood, or P-value of 0.004, NewLink could stop the trial and immediately apply for marketing approval. According to NewLink, this would require the algenpantucel-L patients have an approximately 45% improvement in overall survival over the control group. If the data failed to reveal such an improvement, the study would proceed.

37. For the second interim analysis, conducted when 333 patient deaths were reported in the study, the threshold for meeting statistical significance and proceeding for marketing approval was lower. The statistical significance threshold for the second analysis was a P-value of 0.019, or about a 98% likelihood that algenpantucel-L patients were outliving control group patients because of the NewLink treatment. This would require the algenpantucel-L patients have an approximately 30% improvement in overall survival over the control group. Again, if the data failed to reveal such an improvement, the study would proceed.

38. The final analysis, conducted when 444 patient deaths were reported, set the lowest threshold. Here, if the data did not show a P-value of 0.043, or about 95.5% likelihood that algenpantucel-L patients were outliving control group patients because of the NewLink treatment, the study would not meet the requirements for overall survival. This required a 20% difference between the two arms of the study. In other words, the IMPRESS study was designed

to detect a 30% improvement in overall survival over the control group, and if it did not, the study failed.

Milestone 1: Patient Enrollment

39. Under the FDA approved SPA, the criteria for inclusion in the IMPRESS trial was very strict. According to clinicaltrials.gov, a registry service operating by the U.S. National Institutes of Health, the IMPRESS trial required patients to meet the following rigorous criteria:

- A histological diagnosis of adenocarcinoma of the pancreas confirmed by pathology.
- American Joint Committee on Cancer Stage I or II Pancreatic carcinoma. Patients must have had tumor surgically removed with very few cancer cells remaining.
- Eastern Cooperative Oncology Group (ECOG) Performance Status less than or equal to 2 (at least ambulatory and capable of selfcare).
- Adequate blood plasma proteins.
- Expected survival greater than or equal to 6 months.
- Adequate daily calorie intake.
- Adequate liver and kidney function including, and adequate white blood cell count.
- First vaccination must be within 10 weeks after surgery.
- Informed consent.
- Avoidance of pregnancy.

40. Additionally, patients would be excluded from the trials if any of the following applied:

- Less than 18-years-old.
- Active metastases.
- Other malignancy within five years, unless the probability of recurrence of the prior malignancy is less than 5%.
- History of organ transplant.
- Current, active immunosuppressive therapy.
- Subjects taking chronic systemic corticosteroid therapy.

- Significant heart disease issues within the last six months.
- Active infection or antibiotics within 48 hours prior to study.
- Autoimmune disease.
- Other serious medical conditions or serious illness that may be expected to limit life expectancy to less than 2 years.
- Any condition that would preclude informed consent, consistent follow-up or compliance with any aspect of the study.
- A known allergy the algenpantucel-L treatment.
- Pregnant or nursing women.
- Known HIV positive.

41. These numerous, detailed criteria were exceptionally important because they were designed to correlate with prior pancreatic cancer studies, so that the overall survival estimate for the control group was estimable and based on prior data.

42. Confidential Witness #1 ("CW1"), a NewLink Clinical Research Associate from January 2012 through December 2014, personally spoke with Defendant Vahanian about the design of the IMPRESS trial, but explained that Vahanian was only concerned about getting enough patients for the trial, and was "really pushy" about getting it done within a certain time period. Because of the stringent enrollment criteria, CW1 stated that NewLink had a difficult time finding eligible patients for the IMPRESS study within the required time frame, and as a result of Defendant Vahanian's insistence, the Company flouted the eligibility rules and included patients in the trial whom were not qualified.

43. According to the Company's 8-K filed with the SEC on April 5, 2013 Defendants Link and Vahanian's 2013 year-end bonuses were specifically tied to the Company's ability to enroll patients in the IMPRESS study. Defendants Link and Vahanian not only received cash bonuses of $297,440 and $189,000, respectively, but they also received grants of fully vested

restricted stock unit awards for their "extraordinary performance in 2013."[2] Thus, Defendants Link and Vahanian had a pecuniary motive to enroll patients in the IMPRESS trial as quickly as possible without regard to whether they met the detailed eligibility criteria that was critical to the design of IMPRESS.

44. Nevertheless, on September 17, 2013, the start of the Class Period, Defendants announced in a press release filed on a Form 8-K with the SEC, that IMPRESS' "accrual goal of 722 subjects with surgically resected pancreatic cancer has been met."

45. And despite their disregard of IMPRESS eligibility criteria, the press release actually falsely touted the stringency of the study design and the statistical power stemming from the large patient participation number. In a statement made by Defendant Link, the press release read: "We are confident in the stringency of this study design and the statistical power provided by the large number of patients participating in this trial as we enthusiastically look forward to the clinical results."

Milestone 2: First Interim Data Results

46. Over the next six months, NewLink's stock price began to soar as investors anxiously anticipated positive data results from the first interim review of the IMPRESS trial. Indeed, the stock more than tripled in value from its close on September 17, 2013 when NewLink announced the completion of enrollment to $53.48 on February 25, 2014. During this time, Defendant Link sold 181,000 shares, and Defendant Vahanian sold 177,162 shares for millions of dollars of insider trading profits while the stock was artificially inflated due to their materially false and misleading statements and omissions regarding the IMPRESS study.

[2] *See* NewLink Form 8-K filed with the SEC on January 8, 2014.

47. Then, on March 7, 2014, Defendants issued a press release on Form 8-K, announcing that the DSMC completed its first interim analysis following 222 patient deaths and recommended that the IMPRESS study proceed. Although this was, in fact, bad news because the data did not meet the statistical significance thresholds to seek marketing approval, Defendants misleadingly stated in the press release "it is reassuring that no unexpected safety issues or other concerns were raised by the independent data safety monitoring committee." Shockingly, Defendants actually admit that this was "an anticipated outcome," material information that they never conveyed to investors leading up to the first interim result announcement, and material information that they traded on at great personal profit. Defendant Vahanian is also quoted as saying that "with the first interim analysis behind us, we look forward to continuing the study and to gathering additional, more mature data in support of our mission to provide improved treatment options for patients with pancreatic cancer."

48. Some analysts started to question some of the assumptions NewLink made with regard to the overall survival of the control group; however, Defendants assured them that their estimates were well-founded, and the first interim conclusions did not affect the Company's expectations that IMPRESS would meet its goals. For example, during the March 11, 2014 fourth quarter investor call just days after the first interim results were released, Mara Goldstein of Cantor Fitzgerald and Defendant Link shared the following exchange:

> Goldstein:
> And I just wanted to ask a follow-up on that issue, on the question around control and how the control arm might be acting. Given that the events, the 222nd event happened in February, is it your expectation then that the control arm is performing as you would have figured it in this statistical plan at this point in time based on when you know patients were enrolled in the trial?
>
> Charles Link:
> So we designed a statistical plan that would easily tolerate a control arm in the low 20s. And we did that purposely even though we know historically in the

> United States the outcome for instance of the RTOG-9704 trial was 18.6 months if you include all the patients in that trial. So our view remains the same as we've had all along, which is there may be some benefit from these new chemotherapies that have been approved but the benefit we believe from those treatments will be modest. And we don't believe that there's any fundamental change that has occurred in the United States that is suddenly going to jump the survival of pancreatic cancer patients in the control arm by five or six months. We don't believe that.

49. During the call, Biren Amin of Jefferies & Company also questioned whether the overall survival rate in the control arm was higher than NewLink explained, raising questions about the efficacy of algenpantucel-L, but again, Defendant Vahanian assured Amin that survival expectancy of pancreatic cancer patients was accurate:

> Biren Amin:
> I guess I'll start with HyperAcute pancreas. On the HyperAcute pancreas interim why shouldn't we assume that the control arm would be living beyond the low 20s? So for example could we make the assumption that the control arm is living at 24 or 25 months, and if so what does that do to your stats assumptions? Thanks.
>
> Vahanian:
> I'll start by referencing a recent study that was published by Johns Hopkins Group which demonstrated that for the last three decades going all the way back to the 1980s, 1990s and all the way up to 2011, the survival expectancy of pancreatic cancer was 19.2 months. In all three decades survival did not change in the United States. Looking at the RTOG study, which was the largest pancreatic cancer study completed prior to ours and resected patients, the median survival was 18.6 months. The benefit of GEM/Abraxane combination in metastatic studying up front is 1.7 months. Assuming all of our patients receive GEM/Abraxane follow-up in the salvage setting after recurrence and assuming that even in the recurrent settings they are going to benefit as much as they would in the upfront settings, ***that would move the needle from 18, 19 months to low 20s at best.*** And there is no between [size pool] (inaudible) and similar benefit and again in a metastatic setting. ***The benefits are limited in pancreatic cancer for the last few decades. Considering that it is our expectations, it is our belief that in our study today we don't have any reason to believe that median survival for these patients will be more than low 20s. Nevertheless, our study even though expectations were 18, 19 months, study is designed in the low 20s to be able to -- is powered around that to be able to capture the difference around 20% in survival for the final analysis.*** So a statistical plan has been prepared to capture the difference around 20%, as little as 20%, with control group coming in the low 20s. We believe that is the reason for our confidence for the statistical plan for the study. Chuck, do you want to add to those?

(Emphasis added).

50. Thus, while analysts were correct to question Defendants' assumptions regarding overall survival in the control arm, Defendants were quick to reassure analysts that their skepticism was unfounded and that IMPRESS was designed to capture the necessary statistical power at the final analysis. In another exchange, Amin asked about the timing of the second and final analyses questioning why these events should not be accelerated given the length of time patients had been enrolled in the study:

> Biren Amin:
> Then lastly I guess on the timing of the second and on the final, why given that all the patients are enrolled in the study, why wouldn't we expect to see an acceleration of events now that these patients have been enrolled for quite some time? Thanks.
> ….
> Nicholas Vahanian:
> And if I can comment on your last question, which was about timing for the second and final analysis. If you consider now 222 events took close to four years starting in May 2010, we in fact accept your premise that there will be some acceleration of events occurring because next 111 events we are saying that is going to happen towards the end of 2015 -- 2014 -- which is 9, 10 months from now, 8 to 10 months from now. So that in fact considers that. ***But you have to consider the balance between late impact, or exaggerated impact or late impact of immunotherapy as the time progresses. So it's got to be the balance between patients benefiting more and more from HyperAcute immunotherapy*** and acceleration of events because of a higher number of patients in the pool. That's why we are projecting towards end of 2014. Does that answer your question?

(Emphasis added).

51. While Defendants knew or should have known that patient deaths were occurring at a slower than expected rate because of the erroneously calculated control arm survival rates, Defendant Vahanian directly, and falsely, attributed the delay in patient death reporting to "patients benefiting more and more from HyperAcute immunotherapy" and projected the second and final analyses to take place later than expected because of the "late impact of immunotherapy as the time progresses."

Milestone 3: Second Interim Data Results

52. While the stock price of NewLink decreased slightly after news of the poor first interim analysis results on March 7, 2014, over the next year Defendants were able to sufficiently comfort investors and analysts with materially false and misleading statements and omissions about the promise of the IMPRESS study to re-inflate NewLink's stock back to the same level it had been prior to the announcement of the first interim results.

53. For example, Defendants stated:

- "We initiated these [Phase 3] trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival." (1Q:2014 NewLink Form 10-Q, filed on May 8, 2014).
- "Our fast-track status, orphan drug designation and SPA give us continued confidence in our regulatory strategy." (May 11, 2015 NewLink Press Release).
- "DSMC recommended for the IMPRESS study to continue as planned without any modifications. We were further reassured by the confirmation that there were no unexpected safety concerns." (Charles J. Link, Jr., March 11, 2014 NewLink Earnings Call).
- "We are encouraged by the apparent lengthening of survival in the combined arms of this study…." (Charles J. Link, Jr., March 11, 2014 NewLink Earnings Call).
- "The second interim analysis, which we anticipate will occur later this year…will require approximately a 30% improvement between the two arms based on log rank analysis and the P-value for that is 0.019, what we feel a much more realistic bar in terms of activity to achieve. And we think that there is a significant potential for that interval analysis." (Charles J. Link, Jr., March 11, 2014 NewLink Earnings Call).
- "As we approach the second interim analysis we will continue our commercialization strategy and planning efforts including building the infrastructure needed to support an independent launch in the US market for algenpantucel-L as a treatment for patients with resected pancreatic cancer." (Charles J. Link, Jr., March 11, 2014 NewLink Earnings Call).
- "We are building an extreme commercial oncology team in anticipation of registration and commercialization of algenpantucel-L." (Nicholas N. Vahanian, February 29, 2016 Earnings Call).

54. Based on these statements from management, analysts increased their price targets for NewLink stock:

- "With three-year data from the Phase II trial very close to maturity, overall survival that is 100% greater than historical control is very suggestive of sustained durable response for HyperAcute Pancreas, which, in turn, provides us with a greater level of comfort with the current Phase III program." (Cantor Fitzgerald, March 12, 2014).
- "The company has identified appropriate clinical settings with which to test its technology…has a robust trial design…and has what we see as a scalable, financially reasonable manufacturing process and technology." (Cantor Fitzgerald, March 12, 2014).
- "The company has vetted the trial design with the FDA and has conducted the Phase III with a Special Protocol Assessment (SPA), mitigating the risk that the Agency takes issue with the trial design or other elements once the trial has been completed." (Cantor Fitzgerald, March 12, 2014).
- "[T]he timing of the interim has raised concerns that survival assumptions may be too low and the control arm is performing better than expected. We continue to believe it is too early to be able to draw this conclusion, particularly because trial work suggests immunotherapies impart greater benefit later rather than sooner." (Cantor Fitzgerald, March 12, 2014).
- "We continue to be very positive on HAP, which if approved, could become first-line treatment in pancreatic cancer (one of the most deadly cancers). With the 1st interim analysis for HAP in IMPRESS (at 222 events) having come and gone, we believe that success will be seen on the 2nd interim (at 333 events), given…the longer than expected mean OS seen thus far, and a more reasonable bar for success (a 30% improvement in OS, p=0.02)." (Emphasis in original). (MLV & Co, May 7, 2014).
- "[T]he 2nd interim analysis of HAP in the event driven P3 IMPRESS trial is expected late '14 or (more likely) early '15. Given what we've seen from this asset thus far, we are optimistic the primary endpoints will be met." (MLV & Co, May 16, 2014).
- "**Brimming with HyperAcute Confidence**….The results in this P2 trial lends confidence to the overall success of the HA approach. The pivotal P3 IMPRESS trial for HAP will have a 2nd interim analysis at YE (333 events) and we believe it will be successful…." (Emphasis in original). (MLV & Co, May 30, 2014).
- "**Commercialization Coming into Focus.** As NewLink approaches Phase III data for the HyperAcute pancreas program…the addition of a CFO with a strong commercial background adds a layer of expertise to the company. We believe this a bullish sign coming in front of the second interim look for IMPRESS (at 333 events), likely toward the end of 2014 (stopping will occur

> if a 30% difference is achieved)." (Emphasis in original). (Cantor Fitzgerald, October 2, 2014).

55. With the Company's stock remaining at artificially inflated levels, Defendants Link and Vahanian continued to sell off massive amounts of their NewLink holdings. Between March 7, 2014 and May 11, 2015, Charles Link sold approximately 300,000 shares of NewLink stock for over $10 million. Likewise, Vahanian sold approximately 100,000 shares of his NewLink holdings for over $5 million, including a sale of 60,000 shares on March 5, 2015—his single largest sale of NewLink stock to date—for $49.89 per share, just a few dollars under its all-time high, for nearly $3 million in gross proceeds.

56. Then, on May 11, 2015, NewLink issued a press release filed on Form 8-K with the SEC announcing that the DSMC found that the second interim results again did not justify seeking marketing approval. Again, like the announcement of the first interim results, Defendants downplayed the negative significance of the announcement, stressing that the Company expected the final analysis results to warrant commercialization of algenpantucel-L, stating in relevant part:

> "***We look forward to bringing this study to its planned end point, as algenpantucel-L has the potential to be the first and only FDA approved drug for resected pancreatic cancer, providing additional treatment options to patients, their families and physicians***," said Nicholas N. Vahanian, M.D., President and Chief Medical Officer of NewLink Genetics.
>
> ….
>
> "***Our fast-track status, orphan drug designation and SPA give us continued confidence in our regulatory strategy. With this in mind, we are thoughtfully preparing for regulatory filings and commercial activities associated with a potentially positive outcome of the trial***," said Charles Link, Jr., M.D., Chairman and Chief Executive Officer.
>
> After careful consideration, including a series of communications with the FDA regarding the statistical analysis plan, the Company decided to retain the benefit of the SPA and not to change the statistical analysis plan as defined in the

> original protocol. For the second interim analysis, the independent data safety monitoring committee (DSMC) reviewed available patient data with the originally planned log-rank analysis and sample size recalculation, in all respects consistent with the SPA. No other statistical methods were used. ***The DSMC recommended the study proceed without any modifications, including sample size adjustment, to final analysis. Therefore the Company believes the trial remains powered to determine efficacy upon the occurrence of 444 events***.

(Emphasis added).

57. These statements were materially false and misleading because NewLink was not any closer to obtaining FDA approval to market algenpantucel-L. While the second interim results were undeniably bad news for the viability of algenpantucel-L, Defendants continued to mislead investors to believe that the final results from the IMPRESS trial would be sufficiently positive to proceed to commercialization.

Milestone 4: Final Data Results

58. After the announcement of the negative second interim results, the stock price again dropped significantly, from $52.14 at close on May 11, 2015 to close at $36.55 the next day. Defendants again went into damage control, ramping up its materially false and misleading statements to instill confidence in algenpantucel-L's performance at the final data review.

59. For example, Defendants stated:

- "We are working to expand our manufacturing capabilities. We will provide additional details around our manufacturing progress and commercial supply for algenpantucel-L as we move closer to the potential launch." (Nicholas N. Vahanian, March 11, 2015 Earnings Call).
- "The company has announced that at the time of the second interim analysis, the estimated blended median overall survival in the trial from the time of the randomization was 28.5 months for all patients. Median time from surgery to randomization was approximately 1.5 months. Therefore, median survival from surgery was estimated to be approximately 30 months for all patients in our study. ***We believe that the median months for overall survival from randomization in the control arm is in the low 20s.***" (Nicholas N. Vahanian, March 11, 2015 Earnings Call).

- "When you look at the trends in the overall median in the trial, which have been very encouraging for quite some time though it seem to have stayed consistent and based on that information, ***we are making very large strategic investments in expanding our manufacturing capabilities for vaccines and in developing and laying our initial commercial teams and all the work which is as you know very – a lot to do all the way from reimbursement to logistics, to supply chain, to strategies for commercialization and marketing. So we are doing a tremendous amount of work in this area because of our sense of confidence about what's happening in the trial***." (Emphasis added). (Charles N. Link, Jr., March 11, 2015 Earnings Call).

60. Based on Defendants' statements, analysts increased their price targets for NewLink stock and gave the Company a positive outlook:

- "We have indicated that if IMPRESS does not stop at the interim, investors are likely to assume that this is a failed trial. However, we view the 20% hurdle rate (difference in OS) of the final readout as still achievable, and likely to clinically and commercially relevant should clinical successes occur." (Cantor Fitzgerald, May 12, 2015).

- "With the HyperAcute Pancreas Phase III (IMPRESS) trial continuing to the final look rather than stopping at the second interim look, we think shares will be revalued, with reduced volatility going forward." (Cantor Fitzgerald, May 12, 2015).

- "NLNK reviewed its rationale and early data for its lead HyperAcute candidate, algenpantucel-L, for surgically-resected pancreatic cancer….The company also disclosed that the second interim analysis showed an estimated integrated median overall survival of 28.5 months from the time of randomization (from time of surgery, mgmt estimates ~30 mo). Mgmt acknowledged that salvage tx that may include FOLFIRINOX and/or Abraxane are likely to impact the survival of the pts, but continued to believe that the survival in the control arm, even allowing for the benefit of salvage tx, should still be in the low-twenties (following surgery). Mgmt further reiterated that salvage tx could provide an even greater boost to the active arm due to chemosensitization. Mgmt noted that the rate of deaths in the trial appears to be declining, suggesting a subset of pts who are living well beyond >30 months…." (Jefferies, July 15, 2015).

- "With incremental insight into IMPRESS' second interim analysis revealing an estimated blended median overall survival (OS) of 28.5 months, we are cautiously more optimistic about the outcome for the Phase III trial. If the control arm performs in line with OS in the 22-24 month range, a successful primary endpoint (20% difference) is possible. Additionally, we believe that NewLink has greater flexibility in the statistical methodology at final endpoint

versus interim views, which could also be a factor." (Cantor Fitzgerald, July 15, 2015).

- "We continue to expect final analysis for PIII IMPRESS trial for algenpantucel-L in surgically-resected pancreatic cancer in 2016. The company reiterated that the 2nd interim analysis showed an est integrated median OS of 28.5 months from time of randomization (from time of surgery, ~30 mo), and continued to believe that the survival in the control arm, even allowing for benefit of salvage tx, should be in the low-twenties." (Jefferies, July 31, 2015).

- "With the possibility of efficacy at the final IMPRESS read out (potentially early 2016)…we thing the shares can support a valuation of $62." (Cantor Fitzgerald, July 31, 2015).

- "We believe their vaccine platform is differentiated, and initial results are encouraging. We believe NewLink's cancer vaccine is very different from their peers; it's multi-antigen driven vs single antigen, and has a powerful and unique approach to activate cancer killing. What's more, we are seeing initial signs that it works (median survival of 28.5 months vs. historical survival of around 20 months)." (SunTrust Robinson Humphrey, December 22, 2015).

- **"Positioning themselves for commercialization.** Mr. Paolo Pucci (along with CMO, Dr. Nicholas Vahanian) was appointed to the board in November 2015, increasing the number of board members from 6 to 8. Mr. Pucci adds commercialization experience for oncology drugs. The only other color from the call was their 2016 plan to expand their manufacturing capabilities-expected. These changes reflect NewLink Genetic's preparation for the commercialization of algenpantucel-L." (Emphasis in original). (SunTrust Robinson Humphrey, February 29, 2016).

61. These reports demonstrate that analysts were moved by Defendants' assurances that the overall survival rate of the control arm was still "in the low 20s" despite the much higher blended survival rate, and accepting those assertions regarding algenpantucel-L as "initial signs that it works." Analysts were also encouraged by Defendants' statements regarding their expansion of commercialization capabilities, which were directly linked to confidence in algenpantucel-L's data results.

62. Moreover, Biren Amin from Jefferies issued a "Flash Note" on March 1, 2016 regarding NewLink, drawing attention to the Company's recently filed annual report filed with

the SEC on form 10-K that reported that a clinical site involved in the IMPRESS trial was discovered to be non-compliant with certain Good Clinical Practice (GCP) requirements. Amin raised these issues to NewLink management, but the Flash Note reported that management dismissed the violation as a one-off event that would not have any effect on the trial:

> Key Takeaway
> NLNK's 10-K reported that a clinical site involved in the IMPRESS trial was discovered to be non-compliant with certain GCP requirements. ***We spoke with mgmt and they described it as a minor procedural issue involving one clinician.*** Mgmt does not expect a warning letter from FDA to the site or the need to exclude the "few" patients from this site and confirmed this would not impact timelines, does not violate the SPA, or impact the stats plan.
>
> GCP Non-compliance at One Clinical Site: During a routine audit of data input into the IMPRESS database, NLNK discovered some potential issues which was brought to the attention of the trial site. Upon further investigation by the site, the site "self-reported" to FDA and NLNK that the issues were regarding one clinician. The site is currently working with FDA to implement a remediation plan, NLNK is closely monitoring the progress.
>
> Feedback From NLNK Mgmt: ***NLNK noted that the issues that were brought to the attention of the FDA are procedural in nature and only a minor issue, in their view. The site in question only has "a few" patients enrolled in the IMPRESS trial. IMPRESS requires only 680 pts to make the stats math work and therefore with 722 pts on trial there is a buffer in case any patients need to be excluded, and exclusion of these patients should not have a material impact on the trial.*** A worst case scenario would be the site receiving an FDA warning letter and NLNK excluding the patients from that site. However, mgmt. does not expect this to occur.

(Emphasis added).

63. Contrary to Defendants' statements, however, CW1 witnessed pervasive GCP violations at NewLink with regard to the handling of client data, clinical report forms, and acceptance of patients in the IMPRESS trial that did not qualify under the terms of the SPA. CW1 described numerous regulatory documentation errors at NewLink, which ultimately caused CW1 and several other employees to leave the Company in disgust. CW1 explained that the Company did not have quality control documentation in place before the trials began and

employed not a single person with regulatory experience. Audra Hartwigson was the only person who maintained the Case Report Forms (CRFs) at NewLink and had no experience with the regulations governing the maintenance of clinical trial records, and had no perception of the importance of maintaining clinical trial documents in accordance with regulation. Even though the CRFs contained confidential patient information and therefore should have been secured, they were in a room and everyone had access to them. More poignantly, CW1 described these issues occurring as well over a year before Defendants filed its 2015 10-K and responded to inquiries from Jefferies.

64. Before the inevitable announcement of negative final results, Defendants Charles Link and Vahanian made one final push to sell off their NewLink holdings. Between May 11, 2015 and May 9, 2016, Link sold approximately 260,000 shares of NewLink stock for over $9 million. Vahanian sold approximately 43,000 shares of his NewLink holdings for over $2 million.

65. On May 9, 2016, the last day of the Class Period, after the market closed, the truth regarding algenpantucel-L, the IMPRESS trial, and Defendants' misleading statements and omissions relating thereto emerged when NewLink issued a press release announcing that "[t]he IMPRESS Phase 3 study of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint." In pertinent part, the press release stated:

> ***The IMPRESS Phase 3 study of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint. Overall survival from time of randomization was 29.3 months for both groups combined. There was no statistically significant difference between the two groups. The median survival was 30.4 months and 27.3 months for the control and study groups, respectively.*** There was also no statistical difference for long-term survival. Three year survival was 41.4% and 42.1% and four year survival was 32.6% and 32.7% for the control and study groups, respectively.
> ….

> "In light of these negative results, our scientific and clinical teams will focus on other promising opportunities in our pipeline," said Charles Link, Jr., M.D., Chairman and Chief Executive Officer. "Our lead projects focus on our IDO checkpoint inhibitor technology employing indoximod and GDC-0919. We have substantial near-term catalysts in 2016 for these IDO inhibitor programs, including multiple trial updates from our proprietary and partnered IDO pathway inhibitors, and the financial resources to realize the potential of our product pipeline."

(Emphasis added).

66. Not only did the final results reveal that the overall survival of the control group was considerably longer than Defendants had posited throughout the Class Period, the median survival duration for patients treated with algenpantucel-L was ***3 months shorter*** than those who undergone standard treatment, suggesting that algenpantucel-L actually harmed the patients and shortened their lives.

67. The revelation of these previously undisclosed facts eviscerated the value of NewLink stock by 30.61%, on heavy trading volume, from a closing price of $16.50 per share on May 9, 2016 to close at $11.45 per share on May 10, 2016. And over the next couple days, the price of NewLink stock continued to slide on heavy trading volume and closed at $9.71 on May 12, 2016.

68. The extent of the algenpantucel-L failure came as a shock those following NewLink. For example, senior *TheStreet* columnist Adam Feuerstein, who covers the biotech industry, stated that "NewLink deserves to be investigated for this disastrous pancreatic trial result. A 3-month OS [overall survival] difference in [sic] wrong direction is outrageous."

69. All told, during the Class Period, Link and Vahanian collectively managed to sell over 1,078,174 shares of NewLink stock, representing 81% and 252% of their overall holdings, respectively, while the Company's stock was artificially inflated by their statements, for gross insider trading profits of $36,410,130. Tellingly, neither of them has sold a single share since.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

70. The Class Period begins on September 17, 2013, when NewLink filed a Form 8-K with the SEC and issued a press release entitled "NewLink Genetics Completes Patient Enrollment in Phase 3 Algenpantucel-L (IMPRESS) Clinical Study" (the "September 2013 Press Release"). In the September 2013 Press Release, the Company stated, in part:

> "Our promising Phase 2 results enabled us to successfully collaborate with many major medical centers and the leaders within those institutions," Dr. Link remarked. "To date, IMPRESS is the largest corporate sponsored resected pancreatic cancer study yet conducted. ***We are confident in the stringency of this study design and the statistical power provided by the large number of patients participating in this trial as we enthusiastically look forward to the clinical results***."
>
> "***We are increasingly confident in the progress made with the clinical development of algenpantucel-L***," said Nicholas N. Vahanian, M.D., President, Chief Medical Officer of NewLink Genetics. "***As we enter a critical data collection and analysis phase of the study we are encouraged by the progress made in such a short period of time***. Completion of study enrollment is a critical step towards our mission of bringing better treatment options to pancreatic cancer patients who are in desperate need of more promising alternatives."

(Emphasis added.)

71. The foregoing statements were materially false and misleading when made because the Phase 2 results were not in any way indicative of Phase 3 results and, as such, that those results could not represent the "progress," Vahanian claimed. The Phase 2 study did not even contain a control group against which algenpantucel-L could be measured to determine if the drug had any positive affect over standard treatments. Moreover, Defendants' statements regarding the "stringency of [the IMPRESS] study design and the statistical power provided by the large number of patients participating in this trial" are materially false and misleading, because according to CW1, NewLink disregarded the detailed eligibility criteria for the IMPRESS trials to complete enrollment resulting in patients participating in the IMPRESS trial

who were not qualified. In truth, IMPRESS enrollment was incomplete and the trials fundamentally flawed.

72. On September 27, 2013, NewLink made a presentation at the BioCentury NewsMakers in the Biotech Industry Conference during which Defendants further misrepresented the status of algenpantucel-L's Phase 3 trials and its potential efficacy. Specifically, Nicholas Vahanian stated:

> ***Our Phase III trial, that is getting a lot of attention these days. I'm happy to report -- I'm sure most people heard of it -- that it has completed enrollment, 722 patients.*** Again, proud to say this is the largest corporate-sponsored resected pancreatic cancer study ever done in the world. ***Initiated in May 2010, under a SpA with the Food and Drug Administration, open-label two-arm study, randomized one to one.***

(Emphasis added).

73. The foregoing statements were materially false and misleading when made because algenpantucel-L's SpA had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials. Second, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

74. During the September 27, 2013 BioCentury NewsMakers Conference, Defendant Vahanian also stated as follows:

> I want to actually emphasize one point in the finding of our IMPRESS analysis. People also said, me personally as a biotech investor nibbling on stocks here and there. ***Whenever you see a delay in a trial, you've got to be cautious; I completely accept that.***
>
> ***But please, make this distinction. Pancreatic cancer is significantly different than melanoma.*** When you are staging patients in melanoma and predicting survival, based on stages, can vary between 10 to 30 months or 40 months.
>
> ***In pancreatic cancer, that window is very narrow. Resected pancreatic cancer, patients live 15 months, 19 months. You can look at the last 30 years, all the***

> ***major studies, pancreatic cancer survival -- US-based studies, I want to make that distinction -- survival rates come between 15 to 19, 20 months. That's it. So the flexibility in pancreatic cancer and predicting survival is much narrower than other diseases.***

(Emphasis added).

75. The foregoing statements were materially false and misleading when made because in truth the overall survival for pancreatic cancer patients could be higher than the historical average of "between 15, to 19, 20 months." Thus, these statements misleadingly suggested that the event delay in the IMPRESS trial was related to algenpantucel-L's efficacy.

76. In their Q3 2013 10-Q, NewLink stated, in part:

> Our lead product candidate, HyperAcute Pancreas cancer immunotherapy (algenpantucel-L), or HyperAcute Pancreas, is being studied in two Phase 3 clinical trials; one in surgically-resected pancreatic cancer patients that is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA, and one in locally advanced pancreatic cancer patients. ***We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival***.

(Emphasis added.)

77. The foregoing statements were materially false and misleading when made because the Phase 2 results did not "suggest improvement in both disease-free and overall survival," but merely established good tolerance and a favorable safety profile. NewLink did not initiate the Phase 3 clinical trials "based on encouraging Phase 2 data," as the Phase 2 results were not in any way indicative of Phase 3 results.

78. On March 7, 2014, NewLink filed a Form 8-K with the SEC and issued a press release entitled "NewLink Genetics' Independent Review Committee Recommends Study Continuation Without Modification After Completion of First Interim Analysis of IMPRESS Phase 3 Pancreatic Cancer Trial with Algenpantucel-L" (the "March 7, 2014 Press Release"). In the March 7, 2014 Press Release, the Company stated, in part:

> As part of the planned interim analysis, scheduled to occur following 222 patient events, the independent data safety monitoring committee (DSMC) met to review available patient data. Following their review, the DSMC recommended that the study should proceed as planned, without modification . . . .
>
> "As we have previously emphasized, ***continuation of this study was an anticipated outcome***…"
>
> "***[I]t is reassuring that no unexpected safety issues or other concerns were raised by the independent data safety monitoring committee***," said Dr. Nicholas N. Vahanian, President and Chief Medical Officer of NewLink Genetics. "Now, with the first interim analysis behind us, we look forward to continuing the study and to gathering additional, more mature data in support of our mission to provide improved treatment options for patients with pancreatic cancer."

(Emphasis added.)

79. The foregoing statement was materially misleading because the fact that the DSMC "recommended that the study should proceed as planned" was undeniably bad news in that the IMPRESS trial did not demonstrate efficacy in reviewing data after 222 patients had died. Defendants actually admitted that this was "an anticipated outcome," material information that should have been disclosed to investors prior to this announcement. This information was not "previously emphasized" to investors, as demonstrated by the Company's stock dropping 16% from $37.71 at close on March 6, 2014 to $31.60 at close on March 7, 2013 on heavy trading immediately after the announcement. Moreover, DSMC did not identify any "unexpected safety issues" was not a 'reassurance' that the Phase 3 trials would yield positive results, but merely an ordinary milepost of clinical trials. Finally, the March 7, 2014 press release omitted material information regarding the timing of the first interim analysis in that given when NewLink initiated the IMPRESS trial, the 222 death milestone should have occurred months sooner had their estimate of the overall survival rate of the control group been accurate.

80. On March 11, 2014, NewLink filed a Form 8-K with the SEC and issued a press release entitled "NewLink Genetics Corporation Reports Fourth Quarter and Year End 2013

Financial Results" (the "March 11, 2013 Press Release"). In the March 11, 2014 Press Release, the Company stated, in part:

> ***"We achieved a major milestone in 2013 with the completion of patient enrollment in the algenpantucel-L pivotal Phase 3 IMPRESS study, which we believe to be the largest corporate-sponsored, post-resection pancreatic cancer trial ever conducted. Algenpantucel-L is our most advanced HyperAcute product candidate for pancreatic cancer, and, assuming positive data, we plan to file a BLA for this product in 2015,"*** commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink.

(Emphasis added).

81. The foregoing statements were materially false and misleading because "the completion of patient enrollment" was *not* a "major milestone," as Link claimed, but merely an ordinary milepost of clinical trials. And, according to CW1, NewLink enrolled patients in the Phase 3 trials that were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed. Finally, Defendants had no reason to "assum[e] positive data" from the IMPRESS trial given that they were already knew or should have known that they 1) miscalculated the overall survival of the control arm in the trial; 2) included patients in the trial that did not meet eligibility criteria; and 3) did not follow GCP rules, which would have disqualified patients from the trial.

82. Finally, NewLink also held a call with analysts and investors on March 11, 2014, during which Defendants further misrepresented the status of algenpantucel-L's Phase 3 trials and its potential efficacy. During the call, Defendant Link made numerous false and misleading statements. For example, Defendant Link stated the following:

> ***For algenpantucel-L our lead HyperAcute product, we completed enrollment in our pivotal Phase 3 IMPRESS trial for patients with surgically resected pancreatic cancer in September 2013*** . . . . The DSMC was scheduled to analyze the first interim analysis data during the first week of March after the 222nd event was reached in February. ***DSMC recommended for the IMPRESS study to continue as planned without any modifications***. ***We were further reassured by***

> ***the confirmation that there were no unexpected safety concerns*** . . . . A second interim analysis was planned upon reaching 333 patient events which is expected to occur sometime later this year with the final analysis planned, if needed, at 444 patient events. ***We are encouraged by the apparent lengthening of survival in the combined arms of this study because we believe the body of evidence in prior multi-institution trials of resected pancreatic cancer patients treated in the United States indicates that survival outcomes remain very poor in this unfavorable, unfortunate group of patients***.
>
> ***As we approach the second interim analysis we will continue our commercialization strategy and planning efforts including building the infrastructure needed to support an independent launch in the US market for algenpantucel-L as a treatment for patients with resected pancreatic cancer.***

(Emphasis added).

83. The foregoing statements were materially false and misleading when made because 1) the DSMC did not identify any "unexpected safety concerns" and recommended that the trial continue as planned was not a 'reassurance' that the Phase 3 trials would yield positive results, but merely an ordinary milepost of clinical trials; 2) "the apparent lengthening of survival in the combined arms of the" trial was *not* 'encouraging,' insofar as it did not indicate efficacy; and 3) by indicating that the Company was going forward with commercialization operations, Defendants misleadingly conveyed to investors that they expected algenpantucel-L to be approved for marketing and commercialization, which was not the case. Moreover, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

84. Defendant Link also made the following statement during the March 11, 2014 investor call:

> The second interim analysis, which we anticipate will occur later this year…will require approximately a 30% improvement between the two arms based on log rank analysis and the P-value for that is 0.019, what we feel a much more realistic bar in terms of activity to achieve. ***And we think that there is a significant potential for that interval analysis.***

….

> [W]e designed a statistical plan that would easily tolerate a control arm in the low 20s. And we did that purposely even though we know historically in the United States the outcome for instance of the RTOG-9704 trial was 18.6 months if you include all the patients in that trial. ***So our view remains the same as we've had all along, which is there may be some benefit from these new chemotherapies that have been approved but the benefit we believe from those treatments will be modest. And we don't believe that there's any fundamental change that has occurred in the United States that is suddenly going to jump the survival of pancreatic cancer patients in the control arm by five or six months. We don't believe that.***

(Emphasis added).

85. The foregoing statements were materially false and misleading when made because: 1) NewLink had no basis to believe there was a "significant potential" the DSMC would recommend discontinuing the IMPRESS trial at the second interim analysis; and 2) NewLink had no basis to believe that the benefit from the new chemotherapies would be "modest," and, in fact, the overall survival rate of the control arm, which received standard therapies, was more than 10 months longer than the 18.6 months observed in the RTOG-9704 trial.

86. Defendant Link also stated during the March 11, 2014 call:

> [W]hen we look back at the Phase 2 data I think that what we were struck by and what we didn't really fully understand, as you know, the Phase 2 data didn't have a no-treatment arm so the Phase 2 data was limited. ***But one thing that we know was true is that in the high-dose group at one year, out of the 26 patients, only a single patient had died and that really exceeded any expectation that experts in the field had for what would happen in terms of one-year survival***.
>
> And that one patient, when we looked at that patient, had a 12 centimeter tumor, a fairly enormous tumor from a pancreatic surgery perspective. ***So we felt that that single fact, the survival at one year, was a very strong efficacy signal for the trial in the high-dose group***.
>
> ***And we did believe that we'd seen evidence of dose responsiveness in both lung cancer in pancreatic cancer that then led us to do this 12-month treatment plan***.

> And so since we didn't lose much alpha we thought why not take an early look at this? If there was more dose responsiveness and more duration responsiveness in the clinical effect maybe there could be something of that magnitude, so that's in part why we did it.

87. The foregoing statements were materially false and misleading when made because the "single fact" of participants' survival at one year was *not* "a very strong efficacy signal for the trial in the high-dose group," as Link claimed. Given that the overall median survival of patients with resected pancreatic cancer with standard therapies was over 30 months, the fact that patients taking algenpantucel-L in combination with standard therapies lived over a year is not a signal of efficacy.

88. Finally, Defendant Link stated the following during the March 11, 2014 investor call:

> ***We did make one minor trial modification during the conduct of the trial where we allowed patients to be out to 9 weeks, out to 10 weeks after surgery before enrollment because there were some patients who wanted to get into the trial that just weren't recovering from surgery fast enough. Those patients tend to be a little bit sicker clinically but the surgeons thought that they would be good candidates and so we modified the criteria from 8 weeks to 10 weeks after surgery to still allow them to be permitted into the trial.*** And that modification was done I think in early . . . 2012.

(Emphasis added).

89. The foregoing statement was materially false and misleading when made because it was NewLink's urgent need for trial participants that led the Company to modify the trials to include patients up to 10 weeks out of surgery, *not* the fact that "the surgeons thought that they would be good candidates." Moreover, as described by CW1, there were other patients accepted into the trial who were ineligible other than those who were out of surgery 10 weeks, and thus, the statement that there was only "one minor trial modification is false."

90. Finally, during the March 11, 2014 earnings call, when questioned about the overall survival rate in the control arm, Defendant Vahanian stated as follows:

> I'll start by referencing a recent study that was published by Johns Hopkins Group which demonstrated that for the last three decades going all the way back to the 1980s, 1990s and all the way up to 2011, the survival expectancy of pancreatic cancer was 19.2 months. In all three decades survival did not change in the United States. Looking at the RTOG study, which was the largest pancreatic cancer study completed prior to ours and resected patients, the median survival was 18.6 months. The benefit of GEM/Abraxane combination in metastatic studying up front is 1.7 months. Assuming all of our patients receive GEM/Abraxane follow-up in the salvage setting after recurrence and assuming that even in the recurrent settings they are going to benefit as much as they would in the upfront settings, ***that would move the needle from 18, 19 months to low 20s at best***. And there is no between [size pool] (inaudible) and similar benefit and again in a metastatic setting. ***The benefits are limited in pancreatic cancer for the last few decades. Considering that it is our expectations, it is our belief that in our study today we don't have any reason to believe that median survival for these patients will be more than low 20s. Nevertheless, our study even though expectations were 18, 19 months, study is designed in the low 20s to be able to -- is powered around that to be able to capture the difference around 20% in survival for the final analysis***. So a statistical plan has been prepared to capture the difference around 20%, as little as 20%, with control group coming in the low 20s. We believe that is the reason for our confidence for the statistical plan for the study. Chuck, do you want to add to those?

(Emphasis added).

91. The foregoing statements were materially false and misleading when made because the median overall survival of resected pancreatic cancer patients with standard treatment was not "***in the low 20s"*** but much higher, at over 30 months. Moreover, neither NewLink nor Defendant Vahanian had any basis to believe that the GEM/Abraxane salvage treatments would only increase overall survival "from 18, 19 months to low 20s at best."

92. Vahanian also made the following statement during the March 11, 2014 investor call when questioned about the timing of the second interim and final analyses:

> And if I can comment on your last question, which was about timing for the second and final analysis. If you consider now 222 events took close to four years starting in May 2010, we in fact accept your premise that there will be some

> acceleration of events occurring because next 111 events we are saying that is going to happen towards the end of 2015 -- 2014 -- which is 9, 10 months from now, 8 to 10 months from now. So that in fact considers that. ***But you have to consider the balance between late impact, or exaggerated impact or late impact of immunotherapy as the time progresses. So it's got to be the balance between patients benefiting more and more from HyperAcute immunotherapy*** and acceleration of events because of a higher number of patients in the pool. That's why we are projecting towards end of 2014. Does that answer your question?

(Emphasis added).

93. The foregoing statement was materially false and misleading when made because the "late impact of immunotherapy" (*i.e.*, algenpantucel-L's efficacy) was not driving the increase in overall survival in the IMPRESS trial, as Vahanian suggested, but rather the fact that the overall median survival of patients with resected pancreatic cancer undergoing standard therapies was over 30 months.

94. In their 2013 10-K, NewLink stated, in part:

> In May 2010, we initiated our Phase 3 IMPRESS clinical trial for algenpantucel-L. . . . We completed enrollment in September 2013 with 722 patients and project the first and second interim analyses of data from this study will occur in early 2014 and late 2014, respectively. ***We initiated the IMPRESS trial based on encouraging interim data from our Phase 2 clinical trial that was fully enrolled in March 2010***. . . .

(Emphasis added.)

95. The foregoing statements were materially false and misleading when made because Defendants did *not* initiate the Phase 3 trials "based on encouraging data" from the Phase 2 trial, because those results had no bearing on the potential viability of algenpantucel-L given that they were not measured against a control group. The fact that algenpantucel-L may have demonstrated "good tolerability and a favorable safety profile in the Phase 2 study" had no relevance to the Phase 3 trials. Further, according to CW1, several of the patients enrolled in the

Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

96. In their Q1 2014 10-Q, NewLink stated, in part:

> Our lead HyperAcute product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in two randomized Phase 3 clinical trials. ***The first trial, IMPRESS (Immunotherapy for Pancreatic Resectible Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA.***
>
> **…**
>
> ***We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival.***

(Emphasis added).

97. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; and 2) the Phase 2 results did not "suggest improvement in both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile. Moreover, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

98. In their Q2 2014 10-Q, NewLink stated, in part:

> Our lead HyperAcute product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in two randomized Phase 3 clinical trials. ***The first trial, IMPRESS (Immunotherapy for Pancreatic Resectible Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA.***
>
> ….

> ***We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival.***

(Emphasis added).

99. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; and 2) the Phase 2 results did not "suggest improvement in both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile. Further, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

100. In its Q3 2014 10-Q, NewLink stated, in part:

> Our lead HyperAcute product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in two randomized Phase 3 clinical trials. ***The first trial, IMPRESS (Immunotherapy for Pancreatic Resectible Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA.***
>
> ….
>
> ***We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival.***

(Emphasis added).

101. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; and 2) the Phase 2 results did not "suggest improvement in both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile. Moreover, according to

CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

102. NewLink also held a call with analysts and investors on November 6, 2014 to discuss the third quarter results, during which Defendants misrepresented algenpantucel-L's efficacy by stating that NewLink was preparing to bring it to market. Specifically, Charles Link stated:

> Our view is that, there is a lot of internal work that we need to accomplish much of which is – going on to begin to develop our commercialization team. ***We have done now an extensive amount of commercialization planning***.
>
> We are hiring very actively different members and different components of the commercial teams, some that which we hired, some that which are coming on board and are being interviewed now. ***Our intention is to commercialize the algenpantucel-L, post-resection pancreatic cancer indication in the United States ourselves***.

(Emphasis added).

103. The foregoing statements were materially false and misleading when made because in truth algenpantucel-L had not demonstrated any reliable data of efficacy at the time this statement was made, and by indicating that the Company was going forward with commercialization operations, Defendants misleadingly conveyed to investors that they expected algenpantucel-L to be approved for marketing and commercialization, which was not the case.

104. In their Q4 2014 8-K, NewLink stated, in part:

> "Our pivotal, Phase 3 **IM** munotherapy for **P** ancreatic **RES** ectable cancer **S** tudy, called 'IMPRESS,' is nearing the second interim readout, and we will report when available. ***We are preparing to commercialize this innovative immunotherapy in the United States ourselves, and we are starting to lay the commercial groundwork that will allow us to accelerate access to algenpantucel-L, if approved by the FDA," said Dr. Link***.
> . . .
> The Company revised its timing expectations and stated today that it expects to report on the second interim analysis in the first or second quarter of 2015. ***The possible outcomes for the second interim look include confirmation of***

> ***continuing the study as designed to the pre-planned endpoint. The alternative outcome is a decision to proceed with filing with the FDA on the basis of the interim data due to improvement in overall survival rate as determined by the early stopping rules in the trial's Special Protocol Assessment***.

(Emphasis added).

105. The foregoing statements were materially false and misleading when made because: 1) its commercialization planning was *not* indicative of algenpantucel-L's efficacy and consequential commercial viability; and 2) the third, undisclosed "possible outcome" of the Phase 3 trials was algenpantucel-L's failure.

106. In their 2014 10-K, NewLink stated, in part:

> Our Phase 3 IMPRESS study in surgically-resected pancreatic cancer patients is being performed under an SPA with the FDA. ***Algenpantucel-L has also received Fast Track and Orphan Drug designations from the FDA for the adjuvant treatment of surgically-resected pancreatic cancer***. In May 2010, we initiated our Phase 3 IMPRESS clinical trial for algenpantucel-L . . . . ***We completed enrollment in September 2013 with 722 patients and completed the first interim analysis of data in the first quarter of 2014 . . . . We initiated the IMPRESS trial based on encouraging interim data from our Phase 2 clinical trial that was fully enrolled in March 2010 . . . . Algenpantucel-L has demonstrated good tolerability and a favorable safety profile in the Phase 2 study***.

(Emphasis added).

107. The foregoing statements were materially false and misleading when made because: 1) algenpantucel-L's fast-track status and orphan drug designation had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials; and 2) NewLink did *not* initiate the Phase 3 trials "based on encouraging" Phase 2 results, as "good tolerability and a favorable safety profile" have no bearing whatsoever on the potential viability or success of the Phase 3 trials. Further, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

108. On May 11, 2015, NewLink filed a Quarterly Report on Form 10-Q with the SEC announcing the Company's financial and operating results for the quarter ended March 31, 2015 (the "Q1 2015 10-Q"). In the Q1 2015 10-Q, NewLink stated, in part:

> Our lead product candidate, algenpantucel-L or HyperAcute Pancreas, is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. A second Phase 3 trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), is currently enrolling patients. ***We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival.***
>
> . . .
>
> For the second interim analysis, the independent data safety monitoring committee (DSMC) reviewed available patient data with the originally planned logrank analysis and sample size recalculation, in all respects consistent with the SPA. No other statistical methods were used. ***The DSMC recommended the study proceed without any modifications, including sample size adjustment, to final analysis. Therefore the Company believes the trial remains powered to determine efficacy upon the occurrence of 444 events***.

(Emphasis added).

109. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; 2) the Phase 2 results did not "suggest improvement in both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile; and 3) algenpantucel-L's fast-track status and orphan drug designation, in addition to the fact that "the DSMC recommended that the study should proceed as planned," all had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials. Moreover, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

110. On May 11, 2015, NewLink also issued a press release entitled "NewLink Genetics' IMPRESS Phase 3 Pancreatic Cancer Trial with Algenpantucel-L to Continue Following Second Interim Analysis" (the "May 2015 Press Release").

> "We look forward to bringing this study to its planned end point, as algenpantucel-L has the potential to be the first and only FDA approved drug for resected pancreatic cancer, providing additional treatment options to patients, their families and physicians," said Nicholas N. Vahanian, M.D., President and Chief Medical Officer of NewLink Genetics.
> . . .
> "***Our fast-track status, orphan drug designation and SPA give us continued confidence in our regulatory strategy. With this in mind, we are thoughtfully preparing for regulatory filings and commercial activities associated with a potentially positive outcome of the trial***," said Charles Link, Jr., M.D., Chairman and Chief Executive Officer.

(Emphasis added.)

111. The foregoing statements were materially false and misleading when made because in truth algenpantucel-L's "fast-track status, orphan drug designations and SPA" had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials. Defendant Link's statement that the Company was "thoughtfully preparing" regulatory and commercialization activities was *not* indicative of algenpantucel-L's efficacy and consequential commercial viability.

112. NewLink also held a call with analysts and investors on March 11, 2015, during which Defendants further misrepresented the status of algenpantucel-L's Phase 3 trials and its potential efficacy. Specifically, Defendant Vahanian stated:

> We continue to expect to report the second interim analysis of IMPRESS in this quarter. ***Possible outcomes include the continuation of the study as designed, to the preplanned endpoint, or stop the trial early for efficacy and move towards a BLA filing with the FDA***. Beyond this, we are not going to comment any further on the upcoming interim analysis until we release the results.
> . . .

> ***We are working to expand our manufacturing capabilities. We will provide additional details around our manufacturing progress and commercial supply for algenpantucel-L as we move closer to the potential launch***.

(Emphasis added).

In addition, Defendant Link stated:

> ***When you look at the trends in the overall median in the trial, which have been very encouraging for quite some time though it seem to have stayed consistent and based on that information, we are making very large strategic investments in expanding our manufacturing capabilities for vaccines and in developing and laying our initial commercial teams*** and all the work which is as you know very – a lot to do all the way from reimbursement to logistics, to supply chain, to strategies for commercialization and marketing. ***So we are doing a tremendous amount of work in this area because of our sense of confidence about what's happening in the trial***.

(Emphasis added).

113. The foregoing statements were materially false and misleading when made because: 1) the third, undisclosed "possible outcome" of the Phase 3 trials was algenpantucel-L's failure; and 2) NewLink's commercialization planning was *not* indicative of algenpantucel-L's efficacy and consequential commercial viability. Finally, Link's statement that the Company had "confidence about what's happening in the trial" is at odds with the fact that NewLink was blind to the results.

114. In their Q2 2015 10-Q, NewLink stated, in part:

> Our most advanced program, algenpantucel-L, is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) has completed enrollment of 722 patients with surgically resected pancreatic cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or the FDA. A second Phase 3 trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), is currently enrolling patients. ***We initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival***. Algenpantucel-L has received Fast Track and Orphan Drug designations from the FDA and Orphan Medicinal Product designation from the European Commission for the adjuvant treatment of patients with surgically

> resected pancreatic cancer. . . . As part of [] planned interim analysis, the independent data safety monitoring committee, or DSMC, met to review available patient data. ***As anticipated, following its review, the DSMC recommended that the study should proceed as planned, without modification*** . . . . ***For the second interim analysis, the DSMC reviewed available patient data and recommended the study proceed without modification to final analysis***.

(Emphasis added).

115. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; 2) the Phase 2 results did not "suggest potential to improve both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile; and 3) algenpantucel-L's fast-track status and orphan drug designation, in addition to the fact that "the DSMC recommended that the study should proceed as planned," all had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials. In addition, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

116. NewLink also held a call with analysts and investors on July 31, 2015 to discuss the second quarter results, during which Defendants further misrepresented the status of algenpantucel-L's Phase 3 trials and its potential efficacy. Specifically, Defendant Vahanian stated:

> ***We continue to believe that our HyperAcute immunotherapy program has the potential to improve treatment options across multiple cancer indications***. Our most advanced program, algenpantucel-L, currently is being studied in two Phase 3 trials, IMPRESS for the adjuvant treatment of patients with resected pancreatic cancer; and PILLAR, for patients with locally advanced or borderline resectable pancreatic cancer.
>
> The company has announced that at the time of the second interim analysis, the estimated blended median overall survival in the trial from the time of the

> randomization was 28.5 months for all patients. Median time from surgery to randomization was approximately 1.5 months. Therefore, median survival from surgery was estimated to be approximately 30 months for all patients in our study. ***We believe that the median months for overall survival from randomization in the control arm is in the low 20s.***
>
> . . .
> ***The trial remains under SPA with the FDA and has open drug and fast track status. The initial data had given us confidence to extend our manufacturing capabilities and to proceed with our commercialization plans for algenpantucel-L.***

(Emphasis added).

117. The foregoing statements were materially false and misleading when made because: 1) the Company was blind to the results of the Phase 3 trials, it had no basis to "continue to believe that our HyperAcute immunotherapy program has the potential to improve treatment options across multiple cancer indications"; 2) algenpantucel-L's fast-track status and orphan drug designation had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials; and 3) NewLink's commercialization planning was *not* indicative of algenpantucel-L's efficacy and consequential commercial viability. Most egregiously, however, Vahanian's statements regarding the "estimated blended median overall survival" of 28.5 months and control arm survival "in the low 20s" misleadingly suggested that algenpantucel-L was efficacious.

118. On November 6, 2015, NewLink filed a Quarterly Report on Form 10-Q with the SEC announcing the Company's financial and operating results for the quarter ended September 30, 2015 (the "Q3 2015 10-Q"). In the Q3 2015 10-Q, NewLink stated, in part:

> Our most advanced program, algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) has completed enrollment of 722 patients with surgically resected pancreatic cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug

> Administration, or the FDA. IMPRESS data is expected during 2016. A second Phase 3 trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), is currently enrolling patients and is expected to complete enrollment before the end of 2015. ***We initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival.*** Algenpantucel-L has received Fast Track Designation from the FDA for the adjuvant treatment of Stage I/II resected pancreatic adenocarcinoma in combination with adjuvant gemcitabine chemotherapy and Orphan Drug designation from the FDA for the treatment of pancreatic cancer, as well as Orphan Medicinal Product designation from the European Commission for the adjuvant treatment of patients with surgically-resected pancreatic cancer. . . . . As part of [] planned interim analysis, the independent data safety monitoring committee, or DSMC, met to review available patient data. ***As anticipated, following its review, the DSMC recommended that the clinical trial should proceed as planned, without modification***. The second interim analysis was completed during the second quarter of 2015 following 333 events, which had occurred prior to February 26, 2015. ***For the second interim analysis, the DSMC reviewed available patient data and recommended the clinical trial proceed without modification to final analysis***.

(Emphasis added).

119. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; 2) the Phase 2 results did not "suggest potential to improve both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile; and 3) algenpantucel-L's fast-track status and orphan drug designation, in addition to the fact that "the DSMC recommended that the study should proceed as planned," all had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials. Further, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

120. On February 29, 2016, NewLink filed an Annual Report on Form 10-K with the SEC announcing the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "2015 10-K"). In the 2015 10-K, NewLink stated, in part:

> ***We initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival***. Algenpantucel-L has received Fast Track Designation from the FDA for the adjuvant treatment of Stage I/II resected pancreatic adenocarcinoma in combination with adjuvant gemcitabine chemotherapy with or without adjuvant 5-FU-based chemoradiotherapy and Orphan Drug designation from the FDA for the treatment of pancreatic cancer, as well as Orphan Medicinal Product designation from the European Commission for the treatment of pancreatic cancer.
> . . .
> In May 2010, we initiated IMPRESS, our first Phase 3 clinical trial in patients with surgically-resected pancreatic cancer patients. ***We completed enrollment in September 2013 with 722 patients***. . . . As part of [] planned interim analysis, the independent data safety monitoring committee, or DSMC, met to review available patient data. ***As anticipated, following its review, the DSMC recommended that the clinical trial should proceed as planned, without modification***. The second interim analysis was completed during the second quarter of 2015 following 333 events, which had occurred prior to February 26, 2015. ***For the second interim analysis, the DSMC reviewed available patient data and recommended the clinical trial proceed without modification to final analysis***. We previously announced that concurrent with the second interim analysis, a Kaplan-Meier estimation of overall median survival calculated from the same data set determined that the estimated blended median overall survival in the trial from the time of randomization was 28.5 months for all patients. ***This compares with a longstanding Kaplan-Meier estimated survival of patients with resected pancreatic cancer of approximately 20 months.*** Median time from surgery to randomization was approximately 1.5 months. Therefore, median survival from surgery was estimated to be approximately 30 months for all patients in our IMPRESS clinical trial.

(Emphasis added).

121. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; 2) the Phase 2 results did not "suggest potential to improve both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile; 3) algenpantucel-L's fast-track

status and orphan drug designation, in addition to the fact that "the DSMC recommended that the study should proceed as planned," all had no bearing whatsoever on the potential viability or success of the Phase 3 trials, but were just ordinary mileposts of clinical trials; and 4) the 8.5 month difference between the blended median overall survival from the IMPRESS trial and the estimated survival rate of patients with resected pancreatic cancer in standard treatment was not the result of algenpantucel-L's effectiveness as the statement suggests, but rather because the rate of survival with standard treatment was much longer than 20 months. Also, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

122. NewLink held a call with analysts and investors on February 29, 2016 to discuss the fourth quarter results, during which Defendants misrepresented algenpantucel-L's efficacy by stating that NewLink was preparing to bring it to market. Specifically, Defendant Vahanian stated:

> To sum up, in 2016, we anticipate potential value creating milestones in both our HyperAcute Cellular Immunotherapy and our proprietary IDO pathway inhibitor programs. ***We are building an extreme commercial oncology team an anticipation of registration and commercialization of algenpantucel-L***. If approved, this an oncology product will be the first treatment for patients with resected pancreatic cancer.

(Emphasis added).

Additionally, Defendant Link stated:

> ***In addition, on the manufacturing side, we have expanded the manufacturing capability at NewLink in our Ames facility which will really be used as a source of the product at the time of launch***. And secondarily, we have developed a relationship with the contract manufacturer that can supply additional capacity should launch exceed expectations that will be ready. And one of the goals is to position ourselves that there could be potential for really access programs and certainly recognize that this is a potential lifesaving therapy, should the IMPRESS trial resolves turn favorable later this year.

(Emphasis added).

123. The foregoing statements were materially false and misleading when made because in truth NewLink's commercialization planning was *not* indicative of algenpantucel-L's efficacy and consequential commercial viability.

124. On April 29, 2016, NewLink filed a Quarterly Report on Form 10-Q with the SEC announcing the Company's financial and operating results for the quarter ended March 31, 2016 (the "Q1 2016 10-Q"). In the Q1 2016 10-Q, NewLink stated, in part:

> Our most advanced product candidate, algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, is being studied in two randomized Phase 3 clinical trials. Our first Phase 3 clinical trial, IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) has completed enrollment of 722 patients with resected pancreatic cancer. The primary endpoint for our IMPRESS trial is overall survival. We expect to report top-line IMPRESS results before the end of June 2016. Our second Phase 3 clinical trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), has completed enrollment with over 300 patients. The primary endpoint for our PILLAR trial is overall survival. ***We initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival***. Algenpantucel-L has received Fast Track Designation from the FDA for the treatment of Stage I/II resected pancreatic adenocarcinoma in combination with gemcitabine chemotherapy with or without 5-FU-based chemoradiotherapy and Orphan Drug designation from the FDA for the treatment of pancreatic cancer, as well as Orphan Medicinal Product designation from the European Commission for the treatment of pancreatic cancer.

(Emphasis added).

125. The foregoing statements were materially false and misleading when made because: 1) NewLink did *not* initiate the Phase 3 trials "based on" the Phase 2 results, as those results had no bearing whatsoever on the potential viability or success of the Phase 3 trials; 2) the Phase 2 results did not "suggest potential to improve both disease-free and overall survival," but merely indicated good tolerability and a favorable safety profile; and 3) algenpantucel-L's fast-track status and orphan drug designation had no bearing whatsoever on the potential viability or

success of the Phase 3 trials, but were just ordinary mileposts of clinical trials. Moreover, according to CW1, several of the patients enrolled in the Phase 3 trials were not qualified, thus rendering enrollment incomplete and the trials fundamentally flawed.

126. NewLink also held a call with analysts and investors on April 29, 2016 to discuss the first quarter results, during which Defendants misrepresented algenpantucel-L's efficacy by stating that NewLink was preparing to bring it to market. Specifically, Defendant Link stated:

> We remain blinded to the results of the IMPRESS trial. ***As we have said before, we are anticipating and therefore preparing for the success of the IMPRESS trial, so we continue to advance our plans for the commercial manufacturing of Algenpantucel-L, the filing of the BLA and if it is approved the commercialization of Algenpantucel-L***.
> . . .
> ***As you know, this trial is showing remarkably unexpected projected overall median survival by Kaplan-Meier analysis that was seen on the first and second analyses where we estimate that the survival was 30 months from the time of surgery and the trial as a whole which did a great deal longer than has ever been observed in a U.S. trial before***.
>
> ***So obviously our belief currently and given the investments that we're making in preparation for commercialization, preparation for extended manufacture and all the things that we're doing because we intend to commercialize it ourselves in the United States, we're doing that because we have a strong belief the trial is going to be positive***. But we are blinded to the results, we don't know what the control arm is doing versus the treatment arm. No one knows for sure, right now about that the data and so we're really excited to get in there and dig in this data and obviously since we've announced it is going to occur this quarter, that's on a fairly short event horizon right now.

(Emphasis added).

127. The foregoing statements were materially false and misleading when made because NewLink's commercialization planning was *not* indicative of algenpantucel-L's efficacy and consequential commercial viability. Finally, Link's statements that the Company was "anticipating . . . the success of the IMPRESS trial" and had "a strong belief the trial [was] going to be positive" are at odds with the fact that NewLink was blind to the results. Moreover, the

"***remarkably unexpected projected overall median survival"*** was not due to algenpantucel-L's effectiveness as the statement suggests, but rather because the rate of survival with standard treatment was much longer than Defendants had been conveying to the public.

THE TRUTH IS REVEALED

128. On May 9, 2016, the last day of the Class Period, after the market closed, the truth emerged when NewLink issued a press release announcing that "[t]he IMPRESS Phase 3 study of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint." The press release explained that "[t]he median survival was 30.4 months and 27.3 months for the control and study groups, respectively." In other words, the median survival duration for patients treated with algenpantucel-L was ***3 months shorter*** than those who undergone standard treatment, suggesting that algenpantucel-L actually harmed the patients and shortened their lives. "Given these results," explained the Company, "we are evaluating the future of the HyperAcute® platform." Indeed, the press release quoted Defendant Link stating that "[i]n light of these negative results, our scientific and clinical teams will focus on other promising opportunities in our pipeline."

129. Immediately upon the revelation of these previously undisclosed facts, NewLink stock plummeted 30.61%, on heavy trading volume, from a closing price of $16.50 per share on May 9, 2016 to close at $11.45 per share on May 10, 2016. As investors digested the bad news over the next couple days, the price of NewLink stock continued to slide on heavy trading volume and closed at $9.71 on May 12, 2016.

130. The extent of the algenpantucel-L failure came as a surprise those following NewLink. For example, senior *TheStreet* columnist Adam Feuerstein, who covers the biotech

industry, stated that "NewLink deserves to be investigated for this disastrous pancreatic trial result. A 3-month OS [overall survival] difference in [sic] wrong direction is outrageous."

SCIENTER ALLEGATIONS

131. The Individual Defendants' suspiciously timed stock sales of over $36 million dollars while in possession of material inside information about NewLink in addition to performance bonuses tied to patient enrollment that coincide with facts corroborated by a well-positioned former NewLink employee, support the inference that Defendants acted with scienter in that each Defendant knew and/or recklessly disregarded facts available to them that demonstrated that the public documents and statements issued or disseminated by them individually or in the name of the Company were materially false and misleading.

A. Insider trading by the Individual Defendants Support a Strong Inference of Scienter

132. During the Class Period, the Defendants Link and Vahanian sold massive amounts of their personal holdings of NewLink stock while in possession of material, non-public information, which supports a strong inference of scienter. Not only were their stock sales suspiciously large in quantity, they were suspiciously timed and inconsistent with their pre- and post-Class Period trading practices. Collectively, Defendants Link and Vahanian sold over 1 million shares of NewLink stock over the course of the Class Period for proceeds of over $36 million. Yet, in the nearly six months since the Class Period ended and the artificial inflation was removed from NewLink's common stock, neither Defendant Link nor Defendant Vahanian has sold a single share.

<u>The Amount and Percentage of Shares Defendants Link and Vahanian Sold During the Class Period Was Extraordinary and Inconsistent with Pre- and Post-Class Period Trading Practices</u>

133. To evaluate the Individual Defendants' selling activity, Plaintiffs used the publicly-available trading data that is required to be reported to the SEC on Form 4s in conjunction with data from Thomson Financial. Plaintiffs analyzed the trading by the Individual Defendants that occurred during the Class Period (965 days) and during the period immediately preceding the Class Period (676 days) beginning with the Company's IPO on November 11, 2011 and ending September 17, 2013 together with the period immediately after the Class Period (175 days) beginning on May 9, 2016 through the date of filing (the "Control Period"). The NewLink Form 4s relating to sales of stock by the Defendants Link and Vahanian during the Class Period and the Control Period are incorporated herein by reference.

134. Plaintiffs calculated the total sales by Defendants Link and Vahanian, together with the cash proceeds from such sales, during the Class Period and during the Control Period. Those figures were then compared to identify whether the Individual Defendants' sales during the Class Period were consistent with their sales during the Control Period. During the Class Period, Defendant Link sold 753,001 shares for $24,403,151, but during the Control Period only sold 430,000 shares for $6,592,780. Thus, Link sold 323,001 more shares and made $17,810,371 more in gross profits during the Class Period than the Control Period. Similarly, Defendant Vahanian sold 325,173 shares for $12,006,979 during the Class Period, but during the Control Period only sold 22,000 shares for $398,000. Vahanian therefore sold 303,171 more shares and made $11,608,979 more in gross profits during the Class Period than the Control Period.

135. Put another way, Link sold almost twice as many shares during the Class Period than during the Control Period and for almost 4 times the proceeds. Vahanian sold over ***14 times*** as many shares during the Class Period than the Control Period for over ***30 times*** the proceeds.

Indeed, Defendant Vahanian only made a single sale in the entire Control Period.

136. These analyses reveal that the Defendants Link and Vahanian's Class Period sales of NewLink stock were not only large in absolute terms, but also inconsistent with the Individual Defendants' selling activity outside of the Class Period.

137. Link liquidated **753,001** shares of NewLink stock during the Class Period for a total of **$24,403,151**, which represented between **81%** (based on the beginning of the Class Period) and **266%** (based on the end of the Class Period) of the total shares he had available.[3] In contrast, during the Control Period, Link only sold 430,000 shares for a total of $$6,592,780. Thus, Link's NewLink stock sales during the Class Period are unusual in both dollar and percentage terms, and also out of line with prior selling activity.

138. Vahanian sold **325,173** shares of NewLink stock during the Class Period for a total of **$12,006,979**, which represented between **252%** (based on the beginning of the Class Period) and **522%** (based on the end of the Class Period) of the total shares he had available.[4] Like Link's stock sales, Vahanian's Control Period stock sales stood in stark contrast to his Class Period stock Sales. During the Control Period, Vahanian only sold 22,000 shares for a total of $398,000. Thus, Vahanian's NewLink stock sales during the Class Period are unusual in both dollar and percentage terms, and also out of line with prior selling activity.

The Individual Defendants Suspiciously Adopted and Amended 10b5-1 Plans *During* the Class Period While in Possession of Material Non-Public Information about the Phase 3 Trial; Those Plans Do Not Insulate Individual Defendants' Trading Behavior

[3] Link sold 753,001 shares during the Class Period. His shareholdings amounted to 929,487 shares at the beginning of the Class Period and 282,756 shares at the end of the Class Period. Thus, his sale of 753,001 shares corresponds to 81% (753,001 / 929,487) of his holdings at the beginning of the Class Period, and 266% (753,001 / 282,756) of his holdings at the end of the Class Period.

[4] Vahanian sold 325,173 shares during the Class Period. His shareholdings amounted to 129,144 shares at the beginning of the Class Period and 65,284 shares at the end of the Class Period. Thus, his sale of 325,173 shares corresponds to 252% (325,173 / 129,144) of his holdings at the beginning of the Class Period, and 522% (325,173 / 65,284) of his holdings at the end of the Class Period.

139. In 2000, the SEC adopted Rule 10b5-1, 17 C.F.R. § 240.10b5-1, which provides that a person will be deemed to have traded "on the basis of" material, nonpublic information if they person engaging in the transaction was "aware of" that information at the time of the trade.

140. The SEC also created an affirmative defense to insider trading claims for trades made pursuant to a binding agreement or plan ("10b5-1 plans"). *See id.* at 51, 727-28. Pursuant to SEC Rule 10b5-1(c), a 10b5-1 plan is a potential defense to accusations of insider trading only if it is entered into by an insider "before becoming aware" of inside information, and was established "in good faith and not as part of a plan or scheme to evade the prohibitions" against insider trading.

141. Because of this, insiders are advised to "design a trading plan with the intention that it will not be modified or amended frequently, since changes to the plan will raise issues as to a person's good faith." Thomson West, Corporate Counsel's Guide to Insider Trading and Reporting § 12:26 (2006). Conversely, the adoption and/or modification of these plans while in possession of material, non-public information is highly suspicious and supportive of scienter.

142. While some of the Link and Vahanian's stock sales were made pursuant to 10b5-1 plans, in each case the circumstances of those sales are sufficiently suspicious to overwhelm any inference that they were made in good faith.

Defendant Vahanian

143. Vahanian's first sale transaction during the Class Period took place on November 1, 2013, which was pursuant to a 10b5-1 plan; however, that 10b5-1 plan was adopted ***just three days earlier*** on October 28, 2013, after the Class Period had already started, and at a time when Vahanian was already in possession of material, non-public information, as alleged herein. In these circumstances, even trades according to a 10b5-1 plan are highly suspicious.

144. Furthermore, although sales pursuant to a trading plan should occur with a prescribed, regular pattern of stock sales (for example, 500 shares a month on the 10th day of the month), Vahanian sold irregular amounts of shares at irregular intervals under this first "plan," including 8,000 shares on November 11, 2013; 4,000 shares just four days later; 2,200 shares a week later on November 18, 2013; 3,800 shares the next day on November 19, 2013; 4,500 shares 8 days later on November 27, 2013; 7,500 shares two days later on November 29, 2013; 30,000 shares three days later on December 2, 2013; 27,162 shares a month later on January 3, 2014; 10,000 shares ten days later on January 13, 2014; 35,000 shares the next day on January 14, 2014; 20,000 shares 20 days later on February 3, 2014; and 25,000 shares the next day on February 4, 2014.

145. Vahanian abruptly stopped trading under that 10b5-1 plan just one month before the announcement of the first interim results would decrease the stock price over 25%. Thereafter, Vahanian didn't sell a share over the next year while the stock price was depressed, and only instituted another 10b5-1 plan on January 5, 2015 once Defendants' materially false and misleading statements and omissions inflated the stock price back to the $40+ dollar range. Under this new plan, he began selling shares erratically again. Then, just 17 days after the Company announced the negative second interim results that again decreased the value of NewLink stock, Vahanian amended his 10b5-1 trading plan, which further raises questions as to his good faith. *See* Thomson West, Corporate Counsel's Guide to Insider Trading and Reporting § 12:26 (2006) ("design a trading plan with the intention that it will not be modified or amended frequently, since changes to the plan will raise issues as to a person's good faith.").

146. Vahanian has not sold a single share of stock since the end of the Class Period.

Defendant Link

147. Link's trading was also suspicious. His first Class Period trades were made on September 30, 2013—just two weeks after the beginning of the Class Period when NewLink announced the completion of enrollment in the IMPRESS trial—and pursuant to a 10b5-1plan initiated just 3 months beforehand.

148. Link sold his shares under three different 10b5-1 plans over the course of the Class Period (the first one initiated on 6/17/2013, the second on 6/12/2014, and a third on 5/26/15) with each one covering hundreds of thousands of shares. Yet in on January 28, 2016, approximately four months into the final 10b5-1 plan and when Defendants knew or should have known that the negative final data from the IMPRESS trial would soon be revealed, Link suspiciously amended his 10b5-1 plan. According to Form 4s filed by Link, he only made three more trades under the new plan (two on March 15, 2016 and one on April 7, 2016), all three occurring before the relevant truth regarding IMPRESS was revealed removing the artificial inflation attributable to Defendants' false and misleading statements. Link has not sold a single share since.

B. NewLink's Executive Compensation Plan Provided Substantial Additional Incentives for Defendants to Mislead Investors and Withhold Material Adverse Information

149. The Individual Defendants' compensation structure emphasizes incentives based payoffs. Total compensation consists of three components: 1) base salary; 2) incentives-based cash bonuses; and 3) equity compensation. For example in 2012, Defendant Link's salary was $515,000 and Defendant Vahanian's salary was $400,000. According to the Company's 2013 Proxy Statement, the Individual Defendants' bonus targets for that year specifically "pertained to patient enrollment in the HyperAcute Pancreas Phase 3 clinical trial, which was given a weight of 40%." Indeed, "meeting specific targets for patient enrollment in the HyperAcute Pancreas

Phase 3 clinical trial" was the primary corporate goal for all incentive-based cash bonuses that year. Not only did Link and Vahanian meet their respective goals and earn their bonuses, the Board even approved a supplemental bonus for their "outstanding performance" that year. With the supplemental bonuses, Link earned $311,575 and Vahanian earned $198,000 in incentive based cash bonuses, 60.5% and 49.5% of what Link and Vahanian made, respectively, in salary for that year.

150. The Individual Defendants' bonuses incentivized them to meet enrollment targets in the Phase 3 IMPRESS trial, and explain why, as reported by CW1, Vahanian was "pushy" with clinicians to enroll patients even if they did not meet eligibility requirements. While the Individual Defendants' bonuses (and salaries) paled in comparison to the tens of millions of dollars in insider sales profits Link and Vahanian improperly obtained during the Class Period, their performance bonuses tied to patient enrollment—along with corroborative facts from CW1 that show that Vahanian flouted eligibility requirements in order to push enrollment—bolster a strong inference of Defendants' scienter.

C. Additional Indicia of Scienter

151. In addition to the particularized allegations supported by CW1 that attribute knowledge and/or recklessness to Defendants with regard to NewLink's improper enrollment practices and GCP violations, other facts support a strong inference that Defendants knew or were reckless in not knowing the unlikelihood of algenpantucel-L producing positive results in treating pancreatic cancer in the Phase 3 IMPRESS trial.

152. First, Defendants admitted they anticipated poor IMPRESS trial data before it was released to the public, yet did not convey this to the public. On March 7, 2014, when Defendants announced that the DSMC completed its first interim analysis following 222 patient deaths and

recommended that the IMPRESS study proceed, Defendants actually admitted that this was "an anticipated outcome." Had Defendants conveyed this expectation to investors, they would not have reacted as negatively to the announcement; however, after the March 7, 2014 announcement, the stock price dropped significantly on heavy trading. In truth, Defendants withheld this information in order to keep NewLink's stock price artificially inflated to facilitate the Individual Defendants' stock sales.

153. Second, Defendants are presumed to have detailed, inside knowledge about their principle product. In NewLink's 2016 Form 10-K, the Company acknowledges that algenpantucel-L was NewLink's "lead product candidate" and As the Company's lead treatment candidate during the Class Period, algenpantucel-L and the IMPRESS trial were of critical importance to NewLink. Given that an enormous portion of NewLink's business hinged on the development of the HyperAcute immunotherapy platform, and that algenpantucel-L was the furthest developed of all candidates in the HyperAcute pipeline, Defendants knew or should have known that they overstated the success of the Phase 2 study, that the IMPRESS study design was flawed, that the longer blended overall survival rate likely meant that they had underestimated the overall survival rate of the control group, and that algenpantucel-L was ineffective as a treatment for pancreatic cancer.

154. Moreover, because of the Individual Defendants' positions with the Company, they each had access to the adverse undisclosed information about NewLink's business, operations, products, operational trends, financial statements, markets, and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at

management and Board of Directors meetings and committees thereof, and *via* reports and other information provided to them in connection therewith.

155. Furthermore, because Defendants Link (Chief Executive Officer and Chairman) and Vahanian (President and Chief Medical Officer) were not only the highest-level officers of NewLink during the Class Period, but the Company's co-founders, they were in a position to know facts of critical importance to the Company.

156. By virtue of their high-level positions and the integral role algenpantucel-L played in the Company's success, Defendants Link and Vahanian knew or should have known the adverse facts regarding algenpantucel-L's efficacy that contradicted their public statements. As officers and controlling persons of a publicly-held company whose securities are registered with the SEC pursuant, publicly traded, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

157. Finally, NewLink's financial position and overall business strategy supports a finding of scienter because the Company needs investor support to stay afloat. Although NewLink is seventeen years old, the Company has never generated any revenue from any of its treatment candidates. Indeed, according to the Company's 2016 10-K filing with the SEC,

NewLink has "a history of net losses" and "do not expect to be profitable for the foreseeable future." Because NewLink relies entirely on investor support and contractual agreements with other companies to finance its survival, there is an incentive for the Company to mislead investors and financing companies into believing NewLink has promising treatment candidates.

158. Defendants acted with scienter in that each Defendant knew and/or recklessly disregarded facts available to them that demonstrated that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and, knowingly or recklessly disregarded, and/or substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants participated in the fraudulent scheme alleged by virtue of their receipt of information reflecting the true facts regarding NewLink, their control over the Company's alleged materially misleading misstatements, and/or their associations with the Company, which made them privy to confidential proprietary information concerning NewLink, algenpantucel-L and the IMPRESS trial.

LOSS CAUSATION/ECONOMIC LOSS

159. During the Class Period, Defendants engaged in a scheme to deceive the market, and a course of conduct that artificially inflated NewLink's stock price and operated as a fraud on Class Period purchasers of NewLink's stock by misrepresenting the viability of algenpantucel-L and its likelihood of success in the IMPRESS Phase 3 trial. Ultimately, however, when Defendants' prior misrepresentations came to be revealed to investors, shares of NewLink declined precipitously—evidence that the prior artificial inflation in the price of NewLink's shares was eradicated—and, as a result of their purchases of NewLink stock during

the Class Period at artificially inflated prices, Plaintiffs and other members of the Class suffered economic losses when the truth about the algenpantucel-L was finally and fully revealed and the artificial inflation was removed from price of the Company's stock, *i.e.*, damages under the federal securities laws.

160. Immediately upon the revelation of these previously undisclosed facts, NewLink stock plummeted 30.61%, on heavy trading volume, from a closing price of $16.50 per share on May 9, 2016 to close at $11.45 per share on May 10, 2016. As investors digested the bad news over the next couple days, the price of NewLink stock continued to slide on heavy trading volume and closed at $9.71 on May 12, 2016.

161. The declines in the price of NewLink securities after the truth came to light were a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of NewLink's stock price decline negates any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss suffered by Plaintiffs and the other members of the Class was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of NewLink's securities and the subsequent decline in the value of NewLink's securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

162. The economic loss, *i.e.*, damages suffered by Plaintiffs and other members of the Class, was a direct result of Defendants' misrepresentations and omissions being revealed to investors, and the subsequent significant decline in the value of the Company's shares was also the direct result of Defendants' prior misstatements and omissions being revealed.

APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE

163. Throughout the Class Period, the market for NewLink stock was an efficient market for the following reasons, among others:

a. NewLink securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market, throughout the Class Period;

b. As a regulated issuer, NewLink filed periodic public reports with the SEC and the NASDAQ;

c. NewLink securities were followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;

d. NewLink regularly issued press releases, which were carried by national newswires. Each of these releases was publicly available and entered the public marketplace.

STATUTORY SAFE HARBOR DOES NOT APPLY

164. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized

and/or approved by an executive officer of BlackBerry who knew that those statements were false when made.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

165. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired shares of NewLink common stock between September 17, 2013 and May 9, 2016, inclusive, in the United States or on a United States-based stock exchange and who were damaged when the truth regarding NewLink's lead immunotherapy candidate algenpantucel-L was revealed to the public removing the artificial inflation from the value of NewLink's common stock that had accumulated from Defendants' materially false and misleading statements. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

166. The members of the Class are so numerous that joinder is impracticable. Throughout the Class Period, NewLink common stock was actively traded on an American stock exchange, the NASDAQ. As of May 20, 2016, the Company had 28.8 million shares of common stock issued and outstanding. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by NewLink or its transfer agent and may be notified of the pendency of this action by mail and publication, using the forms of notice similar to those customarily used in securities class actions.

167. Plaintiffs' claims are typical of the claims of the members of the Class as

Plaintiffs and all members of the Class were similarly affected by Defendants' conduct in violation of the federal securities laws that is complained of herein.

168. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class and have retained counsel competent and experienced in class action and securities litigation.

169. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members. A classwide proceeding will generate common answers to the following questions of law and fact common to the Class, among others:

(a) whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) whether Defendants made materially untrue and/or misleading statements/omissions during the Class Period; and

(c) whether the members of the Class have sustained damages and the proper measure of damages.

170. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, as joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action. Plaintiffs' allegations stem from Defendants' issuance of materially false and/or misleading statements and omissions during the Class Period contained in SEC filings, Company releases, and conference calls with analysts. These statements and omissions concealed true,

adverse facts about, *inter alia*, algenpantucel-L and its likelihood of commercialization.

CLAIMS FOR RELIEF

COUNT I

(For Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants—NewLink, Link and Vahanian)

171. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

172. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (a) deceive the investing public regarding the viability of algenpantucel-L, the Company's lead immunotherapy candidate, the likelihood that it would meet the goals of the IMPRESS Phase 3 study, and the true value of NewLink stock; (b) enable Defendants to inflate and to maintain the artificial inflation in the price of Company stock throughout the Class Period; and (c) cause Plaintiffs and other members of the Class to purchase NewLink common stock at artificially inflated prices, resulting in damages after the truth was revealed and the artificial inflation was removed from the price of the stock. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, jointly and individually (and each of them) took the actions set forth herein.

173. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud upon the purchasers of the Company's stock in an effort to maintain an artificially high market price for NewLink stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants are sued as primary participants in the wrongful and illegal

conduct charged herein and as controlling persons as alleged below.

174. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of NewLink as specified herein.

175. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of NewLink's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about NewLink and its business, operations, performance, and prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of NewLink stock during the Class Period.

176. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts. Defendants' material misrepresentations and/or omissions were done knowingly or with reckless disregard for the purpose and effect of concealing the truth regarding NewLink's business and algenpantucel-L from the investing public and supporting the artificially inflated price of its stock. As demonstrated by Defendants' material misstatements and omissions concerning the Company's business, operations, performance, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the

misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by recklessly refraining from taking those steps necessary to discover whether those statements were false or misleading.

177. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of NewLink stock was artificially inflated during the Class Period. In ignorance of the fact that the market price of NewLink stock was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired NewLink stock during the Class Period at artificially high prices and were damaged after the truth regarding the Company was revealed, which removed the artificial inflation from NewLink's stock.

178. The primary liability of Defendants Link and Vahanian arises from the following facts: (a) Defendants were high-level executives at the Company during the Class Period and members of the Company's management team or had control thereof; (b) Defendants, by virtue of their responsibilities and activities as senior officers of the Company were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (c) all of these Defendants enjoyed significant personal contact and familiarity with each other and were advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's business, operations, performance, and prospects at all relevant times; and (d) Defendants were aware of the Company's dissemination of information to the investing

public which they knew or recklessly disregarded was materially false and misleading.

179. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for NewLink stock. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding algenpantucel-L and the IMPRESS study, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their NewLink stock, or, if they had acquired such stock during the Class Period, they would not have done so at the artificially inflated prices which they paid.

180. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

181. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases of the Company's stock during the Class Period.

COUNT II

(For Violations of §20(a) of the Exchange Act against Individual Defendants Link and Vahanian)

182. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

183. Defendants Link and Vahanian acted as controlling persons of NewLink within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had

the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendants Link and Vahanian were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

184. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

185. As set forth above, NewLink and Defendants Link and Vahanian, each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants Link and Vahanian also are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period and the related damages resulting after the true facts were revealed and the artificial inflation was removed from the price of the stock.

COUNT III

(For Violations of §20A of the Exchange Act against Individual Defendants Link and Vahanian)

186. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

187. This Claim is alleged against Defendants Link and Vahanian.

188. While NewLink securities traded at artificially inflated and distorted prices, Defendants Link and Vahanian personally profited by selling approximately 750,000 and 325,000 shares of NewLink securities, respectively, while in possession of adverse, material non-public information about NewLink, acquiring a total of approximately $36 million in illegal insider trading proceeds between the two of them.

189. Lead Plaintiffs purchased NewLink securities contemporaneously with Link and Vahanian's sales. Charles Link sold 10,000 shares on November 10, 2014 and Lead Plaintiffs purchased 1,400 shares that same day, and 6,400 shares the next day on November 11, 2014. Link sold 6,300 shares on December 4, 2014 and Lead Plaintiffs purchased 4,500 shares the next day on December 5, 2014. Charles Link sold 5,000 shares on January 6, 2015 and Lead Plaintiffs purchased 3,700 shares that same day. Vahanian sold 10,000 shares on April 1, 2015 and Lead Plaintiffs purchased 400 shares that same day, and 4,900 shares the following day on April 2, 2015. Charles Link sold 20,000 shares on August 5, 2015 and Lead Plaintiffs purchased 575 shares the next day on August 6, 2015.

190. By virtue of Link and Vahanian's participation in the scheme to defraud investors described herein, and/or Link and Vahanian's sales of stock while in possession of material, non-public information about the adverse information detailed herein, Link and Vahanian violated the Exchange Act and applicable rules and regulations thereunder.

191. Lead Plaintiff and all other members of the Class who purchased shares of NewLink stock contemporaneously with the sales of NewLink stock by Charles Link and Vahanian: (i) have suffered substantial damages in that they paid artificially inflated prices for NewLink stock as a result of the violations of §§10(b) and 20(A) and Rule 10b-5 herein

described; and (ii) would not have purchased NewLink stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by Defendants' false and/or misleading statements.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

1. Determining that this action is a proper class action, certifying Plaintiffs as Class representatives under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Lead Counsel;

2. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

3. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

4. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder; and

5. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: November 10, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed on November 10, 2016, and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on November 10, 2016.

/s/ Kim E. Miller
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